Checklist for Traditional 510(k)s

传统 510(k)检查清单

The following information is not intended to serve as a comprehensive review. FDA recommends that the submitter include this completed checklist as part of the application.

以下信息并不旨在作为全面审查。FDA 建议提交者将此已完成的检查清单作为申请的一部分。

Preliminary Questions

初步问题

> Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)
>
> 阴影框中的答案表示需要与指定中心顾问进行咨询。（本节中勾选的框代表 FDA 在行政审查时对这些问题的初步评估。）

1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a **510(k)** ?

   该产品是设备（根据 FD&C 法第 201(h)节）还是组合产品（根据 21 CFR 3.2(e)）且其组成部分为设备，需在**510(k)**中进行审查吗？

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果它似乎不是设备（根据 FD&C 法案第 201(h)节）或这样的组合产品（根据 21 CFR 3.2(e)），或者您不确定，请咨询 CDRH 产品管辖官员或 CBER 产品管辖官员以确定适当的行动，并通知管理层。在下面的评论部分提供产品管辖官员的决定/建议/行动的摘要。

If the product does not appear to be a device or such a combination product, mark "No."

如果该产品似乎不是设备或此类组合产品，请标记“否”。

Comments:

评论：

2. Is the submission with the appropriate Center?

2. 提交是否在适当的中心？

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果产品是设备或包含设备成分的组合产品，它是否需要由接收提交的中心进行审查？如果您认为提交不在适当的中心，或者您不确定，请咨询 CDRH 产品管辖官或 CBER 产品管辖官，以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

If submission should not be reviewed by your Center mark "No."

如果提交不应由您的中心审核，请标记为“否”。

Comments:

评论：

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

   如果已提交针对该设备或包含设备成分的组合产品的指定请求（RFD），并分配给您的中心，请识别 RFD 编号并确认以下内容：

   (a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?

   (a) 该设备或组合产品是否与 RFD 提交中呈现的相同（例如，设计、配方）？

   (b) Are the indications for use for the device or combination product identified in the $510(k)$ the same as those identified in the RFD submission?

   (b) 设备或组合产品的使用指示在 $510(k)$ 中是否与 RFD 提交中识别的相同？

If you believe the product or the indications presented in the $510(k)$ have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果您认为在$510(k)$中呈现的产品或适应症与 RFD 有所变化，或者您不确定，请咨询 CDRH 产品管辖官或 CBER 产品管辖官，以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."

如果上述任一问题的答案是否定的，请标记为“否”。如果没有 RFD，请标记为“N/A”。

Comments:

评论：

4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act?

该提交是否为一种组合产品，其中包含作为组成部分的药物，该药物具有与根据 FD&C 法第 503(g)(5)(C)(ii)-(v)节获得专 exclusivity 的批准药物相同的活性成分？

If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果“是”，请联系 CDRH 产品管辖官或 CBER 产品管辖官以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

Comments:

评论：

5. Is this device type eligible for a **510(k)** submission?

该设备类型是否符合 **510(k)** 提交的资格？

If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."

如果 510(k)似乎不合适（例如，属于 III 类且需要 PMA，或属于 I 类或 II 类且免于 510(k)），请在接受审查期间咨询相关的 CDRH 或 CBER 工作人员，提供与他们讨论的摘要，并在下面的评论部分中指明他们的建议/行动。如果 510(k)不是适当的监管提交，请标记为“否”。

Comments:

评论：

6. Is there a pending PMA for the same device with the same indications for use?

6. 是否有针对相同适应症的相同设备的待审 PMAs？

If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.

如果“是”，请咨询您的管理层和 CDRH 产品评估与质量办公室/监管项目办公室/监管项目部 1（提交支持）（OPE

Q/ORP/DRP1）或适当的 CBER 工作人员，以确定适当的行动。

Comments:

评论：

7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

   如果已提交临床研究，提交者是否受到申请完整性政策（AIP）的约束？

If "Yes," consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action.

如果“是”，请咨询 CDRH 产品评估与质量办公室/临床证据与分析办公室/临床科学与质量部（OPEQ/OCEA/DCEA 1）或 CBER 合规与生物制品质量办公室/检查与监测部/生物研究监测分支（OCBQ/DIS/BMB），以确定适当的行动，提供与他们讨论的摘要，并指明他们的建议/行动。

If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.

如果没有提交临床研究，请标记为“无”。请在 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list 上查看 AIP 列表。

Comments:

评论：

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.

  如果对 1 或 2 的回答似乎是“否”，则停止对 510(k)的审查，并联系 CDRH 产品管辖官或 CBER 产品管辖官。

- If the answer to 3 a or 3 b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.

  如果对 3 a 或 3 b 的回答似乎是“否”，则停止审查并联系 CDRH 产品管辖官或 CBER 产品管辖官。

- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.

  如果第 4 项的答案是“是”，请联系 CDRH 产品管辖官或 CBER 产品管辖官，提供与他们讨论的摘要，并说明他们的建议/行动。

- If the answer to 5 is " No ", the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or

  如果第 5 项的答案是“否”，主审查员应咨询部门管理层和其他中心资源，以确定适当的行动。请注意，对于明显不符合510(k）提交条件的设备（例如需要 PMA 的 III 类设备类型或

class I/II and $510(k)$ exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

对于 I/II 类和$510(k)$豁免设备，这可能被视为拒绝接受提交的依据。对于触及豁免限制的 I/II 类、510(k)豁免设备提交的 510(k)不会基于此理由被拒绝。

- If the answer to 6 is "Yes," then stop review of the $510(k)$, contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.

如果第 6 问的答案是“是”，则停止对$510(k)$的审查，联系 CDRH/OPEQ/ORP/DRP1 或适当的 CBER 工作人员。

- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

如果第 7 问的答案是“是”，请联系 CDRH/OPEQ/OCEA/DCEA1 或 CBER/OCBQ/DIS/BMB，提供与 DCEA1 或 BMB 工作人员讨论的摘要，并说明他们的建议/行动。

Organizational Elements

组织元素

Failure to include these items should not result in an RTA designation.

未能包含这些项目不应导致 RTA 标记。

		Yes 是的	No 不	*Page # *页面#
	*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. *提交者在提交材料时应附上清单，并标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。			
1. 1.	Submission contains a Table of Contents. 提交包含目录。	☐	☐	
2. 2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.). 每个部分都有标签（例如，标头或标签指定设备描述部分、标签部分等）。	☐	☐	
3. 3.	All pages of the submission are numbered. All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...). 提交的所有页面都应编号。 所有页面应以可以通过页码引用信息的方式编号。这可以通过对整个提交进行连续编号，或对某个部分内的页面进行编号（例如，12-1，12-2...）来完成。	☐	☐	
4. 4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) If type of 510(k) is not designated, review as a Traditional 510(k). 510(k)的类型已确定（即，传统、简化或特殊）。如果未指定510(k)的类型，请作为传统 510(k)进行审查。	☐	☐	

Comments:

评论：

Elements of a Complete Submission (RTA Items)

完整提交的要素（**RTA** 项目）

(21 CFR 807.87 unless otherwise indicated)

（**21 CFR 807.87**，除非另有说明）

Submission should be designated RTA if not addressed.

如果未解决，提交应标记为 **RTA**。

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.

  任何“否”回答将导致“拒绝接受”的决定；然而，FDA 工作人员有权决定缺失的项目是否需要，以确保提交在行政上是完整的，从而允许提交被接受，或者在 RTA 审查期间与提交者互动请求缺失的检查清单项目。

- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

  每个检查表上的元素都应在提交中得到处理。提交者可以为任何被认为不适用的标准提供省略的理由。如果提供了理由，则该标准被视为存在（是）。在审查提交时，将考虑对理由的评估。

  Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

  如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 随提交材料一同提交此清单的提交人，应标明所需信息所在页码。若需额外空间注明支持性信息的位置，可在对应项目的评论栏中说明。				Yes 是	No 否	N/A 不适用	*Page# 页码
A.	Administrative 管理方面						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) 用于支持本次提交的所有内容均应以英文书写（包括测试报告、文献文章等的翻译）。		☐	☐		
		Comments: 评论：					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download): 提交材料需标明以下内容（美国食品药品监督管理局（FDA）建议使用器械和放射健康中心（CDRH）的上市前审评提交材料封面表单（3514 号表单，可从 https://www.fda.gov/media/72421/download 下载获取））：					
		a.	Device trade/proprietary name 器械的商品名称 / 专有（品牌）名称	☐	☐		
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion 器械类别和评审小组，或分类法规，或说明器械尚未分类及其理由。	☐	☐		
		Comments: 评论：					
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling) See recommended format (https:// www.fda.gov/media/86323/download). 提交材料应包含一份使用适应症声明，并标明该器械为处方药（Rx）和 / 或非处方药（OTC）（另见《联邦法规》第 21 编第 801.109 条，以及美国食品药品监督管理局（FDA）的最终规则《标签中符号的使用》（《联邦纪事》第 81 卷，第 38911 页），可通过 https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling获取）。 查看推荐格式（https://www.fda.gov/media/86323/download）。		☐	☐		
		Comments: 评论：					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review. 提交材料需包含一份 510（k）总结或 510（k）声明，510（k）总结的内容请参考《联邦法规》第 21 编第 807.92 条，510（k）声明的内容请参考《联邦法规》第 21 编第 807.93 条。内容的充分性将在实质性审评过程中进行评估。		☐	☐		
		Comments: 评论：					

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果该项内容存在，请勾选 “是”；如果该项内容不需要，请勾选 “不适用（N/A）” ；如果该项内容缺失但又是必需的，请勾选 “否”。 随提交材料一并提交此清单的提交者，应标明所要求信息所在的页码。如果需要额外的空间来注明支持性信息的位置，请在相应项目的注释部分进行说明。				Yes 是	No 否	N/A 不适用	*Page# 页码
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(1) See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement). 提交材料需包含一份 510 (k) 总结或 510 (k) 声明。 510 (k) 总结的内容请参考《联邦法规》第 21 编第 807.92 条，510 (k) 声明的内容请参考《联邦法规》第 21 编第 807.93 条。内容的充分性将在实质性审评过程中进行评估。			☐	☐	☐	
		Comments: 评论：						
	6.	Submission is a class III510(k)Device. Select "N/A"only if submission is not a class II 510(k). 提交的是三类 510 (k) 器械的相关材料。 仅当提交的不是二类 510 (k) 器械的相关材料时，选择 “不适用（N/A）”。			☐	☐	☐	
		a.	Contains class II Summary and Certification per 21 CFR 807.87(k). See recommended content(https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary).Select "N/A"only ifsubmission is not a class II510(k) 包含符合《联邦法规》第 21 编第 807.87 (k) 条规定的二类（器械）总结和认证内容。 查看推荐内容（https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary）。仅当提交的材料并非二类 510 (k)（医疗器械相关材料）时，选择“不适用（N/A）”。	☐	☐	☐	
		Comments: 评论：						
	7.	Submission contains clinical data. Select"N/A"if the submission does not contain clinical data.If "N/A"is selected,parts a,b,and c below are omitted from the checklist. 提交材料包含临床数据。 如果提交材料中不包含临床数据，请选择 “不适用（N/A）”。如果选择了 “不适用（N/A）”，那么以下清单中的 a、b 和 c 部分将被省略。			☐		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454,available at https://www.fda.gov/media/70465/download)or Disclosure (FDA Form 3455,available at https://www.fda.gov/media/69872/download)information for each covered clinical study included in the submission Select "N/A"if the submitted clinical data is not a "covered clinical study"as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators. 提交材料包括针对所提交内容中包含的每项受监管临床研究的已填写完整的财务认证信息（美国食品药品监督管理局（FDA）3454 表格，可从 https://www.fda.gov/media/70465/download下载获取）或披露信息（FDA 3455 表格，可从https://www.fda.gov/media/69872/download下载获取）。 如果所提交的临床数据并非标题为《临床研究者的财务披露》（可从 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators获取）的指南中所定义的 “受监管临床研究”，则选择 “不适用（N/A）” 。	☐	☐	☐	

		Yes 是的	No 不	N/A 不适用	*Page # *页面#
	Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。				
b. b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manualsforms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j). 提交包括符合 ClinicalTrials.gov 数据银行要求的合规性认证（请参见 FDA 表格 3674，可在 https://www.fda.gov/about-fda/reports-manualsforms/forms 获取）（42 U.S.C. 282(j)(5)(B)），适用于提交中包含的每个相关设备临床试验。 如果提交的临床数据不是 FDAAA 第八章第 801(j)条款中定义的“适用设备临床试验”，请选择“N/A”。	☐	☐	☐	
c. c.	Statements of Compliance for Clinical Investigations Select " N/A " if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence. For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019. Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information. 临床研究合规声明 如果提交不包含任何来自研究的临床数据（如 21 CFR 812.3(h)所定义）以证明实质等效性，请选择“N/A”。 对于涉及美国（US）和美国以外（OUS）地点的多中心临床研究，部分（i）应针对美国地点进行处理，部分（ii）应针对美国以外地点进行处理。21 CFR 812.28 适用于 2019 年 2 月 21 日或之后招募第一名受试者的所有美国以外的临床研究。 有关更多信息，请参阅题为“接受临床数据以支持医疗器械申请和提交 - 常见问题”的指导文件，网址为 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked。	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交材料时应附上清单，并应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

			Yes 是的	No 不	N/A 不适用	*Page # *页面#
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。						
8. 8.		submission identifies prior submissions for the same device uded in the current submission (e.g., submission numbers for or not substantially equivalent [NSE] determination, prior ted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). s that there were no prior submissions for the subject ce. r submissions (or no prior submissions) for this device ld be included in Section F (prior related submissions) of CDRH Premarket Review Submission Cover Sheet form m 3514, available at s://www.fda.gov/media/72421/download). This information also be included in the Cover Letter (i.e., as a statement that were no prior submissions for the device or a listing of the ber(s) of the prior submissions). 提交识别当前提交中使用的相同设备的先前提交（例如，针对不实质等效[NSE]判定的提交编号，先前的 510(k)提交或撤回，Q-提交，IDE，PMA 等）。 确认该设备没有先前的提交。 r 提交（或没有先前提交）应包含在 CDRH 预市场审查提交封面表格m 3514 的 F 部分（先前相关提交）中，表格可在 s://www.fda.gov/media/72421/download 获取。该信息也应包含在封面信中（即，作为声明，表明该设备没有先前提交或列出先前提交的编号）。	☐	☐		
	a. a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review. Select " N/A " if the submitter states there were no prior submissions. 如果之前有提交，提交者已确定在当前提交中与该设备之前提交的实质等同性判定相关的任何问题是如何解决的。 为满足此标准，建议提交中包含一个单独的部分，列出之前的提交编号、FDA 反馈的副本（例如，信函、会议记录），以及说明在提交中如何或在哪里解决了这些之前的反馈。请注意，反馈解决的充分性将在实质审查期间进行评估。 如果提交者声明没有之前的提交，请选择“N/A”。	☐	☐	☐	
		Comments: 评论：				
9. 9.		submission utilizes voluntary consensus standard(s) (See on 514(c) of the FD&C Act). This includes both FDAgnized and non-recognized consensus standards. Select A" if the submission does not utilize voluntary consensus dards. 提交利用自愿共识标准（见 FD&C 法案第 514(c)条）。这包括 FDA 认可和未被认可的共识标准。如果提交不使用自愿共识标准，请选择“A”。	☐		☐	
	a. a.	The submission cites FDA-recognized voluntary consensus standard(s). 提交引用了 FDA 认可的自愿共识标准。	☐		☐	


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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but
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*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交材料时应附上清单，并标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。				Yes 是的	No 不	N/A 不适用	*Page # *页面#
		a. a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act. 提交包括适当的专利声明或认证，以及提交者将根据需要发出通知的声明。请参见 FD&C 法案第 503(g)(5)(A)和(C)节。		☐	☐		
Comments: 评论：							
B. B.	Device Description 设备描述						
	12. 1 2.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. If " N/A " is selected, parts a and b below are omitted from the checklist. 该设备具有针对特定设备的指导文件、特殊控制和/或适用于该设备描述的特定设备分类法规中的要求，这些要求适用于所述设备。 如果选择“N/A”，则下面的部分a和b将从清单中省略。		☐		☐	
		a. a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select " N/A " if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的设备描述建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息的理由或上述任何替代方法，请选择“否”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。		☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

*提交者在提交材料时应标识包含清单

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

comments section for an element if additional space is needed to identify

如果需要额外空间来识别，请为一个元素添加评论部分

the location of supporting information.

支持信息的位置。

*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Yes 是的	No 不	N/A 不适用	* Page # * 页 #
☐	☐	☐ 是 否 不适用 * 页码 ☐ ☐ ☐	

Comments:

评论：

13. 13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling). 描述性信息在提交中是存在且一致的（例如，设备描述部分与标签中的设备描述一致）。	☐	☐		
14. 14.	Comments: The submission includes descriptive information for the device, including the following: 评论： 提交包括设备的描述性信息， 包括以下内容：				
a. A description of the principle of operation or mechanism of action for achieving the intended effect. 实现预期效果的操作原理或作用机制的描述。	☐	☐			
b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. 对拟议使用条件的描述，例如： 植入物的外科技术；使用的解剖位置； 用户界面；设备如何与其他设备交互； 以及/或设备如何与患者交互。	☐	☐			
c. A list and description of each device for which clearance is requested. Select 'N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc. 请求批准的每个设备的列表和描述。 如果只有一个设备或型号，请选择“N/A”。 “设备”可以指型号、部件编号、各种尺寸等。	☐	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

*提交者在提交材料时应标识包含清单

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

comments section for an element if additional space is needed to identify

如果需要额外空间来识别某个元素，请在评论部分填写

the location of supporting information.

支持信息的位置。

Yes 是的	No 不	N/A 不适用	∗ Page # ∗ 页 #
☐	☐ 是 否 不适用 ∗ 页码 ☐ ☐		

Comments:

评论：

15. 15.	Device is intended to be marketed with accessories and/or as part of a system. Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist. 设备旨在与配件和/或作为系统的一部分进行市场销售。 如果设备不打算与配件和/或作为系统的一部分进行市场销售，请选择“无”。如果选择“无”，则以下 a-c 部分将从清单中省略。	☐		☐	
a. Submission includes a list of all accessories to be marketed with the subject device. 提交包括与主题设备一起销售的所有配件清单。	☐	☐			
b. Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. Select 'N/A" if the accessory (ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications. 提交包括对每个附件的描述（如上述第 14a、14b 和 14d 项所述）。如果附件已被之前批准或免除，并且拟议的使用指示与已批准的指示一致，请选择“N/A”。	☐	☐	☐		
c. A 510(k) number is provided for each accessory that received a prior 510(k) clearance. AND 每个获得先前 510(k)批准的配件都提供一个 510(k)编号。	☐	☐			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. *提交者在提交材料时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
C. Substantial Equivalence Discussion C. 实质等同性讨论				
16. Submitter has identified a predicate device(s), including the following information: 16. 提交者已识别出一个或多个对照设备，包括以下信息：				
a. Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status). a. 提供了前驱设备标识符（例如，510(k)号、De Novo 号、重新分类的 PMA 号、分类法规参考，如果免除（例如，21 CFR 872.3710），或声明前驱设备是修订前设备）。 对于修订前设备，提供信息以记录修订前状态。 有关记录修订前状态的信息可在线获取（https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status）。	☐	☐		
b. The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing. b. 所识别的前提设备在整个提交中是一致的（例如，实质等同性部分中识别的前提设备与510(k)摘要中列出的设备（如适用）以及在比较性能测试中使用的设备相同）。	☐	☐		
Comments: 评论：				
17. Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], " available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics. 17. 提交包括对前体设备和主体设备的比较，以及讨论主体设备与前体设备之间的任何差异为何不影响安全性和有效性 [参见 FD&C 法案第 513(i)(1)(A)节和 21 CFR 807.87(f)]。 有关比较预期用途和技术特征的更多信息，请参阅 FDA 指导文				

		件“510(k)计划：评估上市前通知[510(k)]中的实质性等效性”，可在 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k 获取。				

		Yes 是的	No 不	N/A 不适用	*Page # *页面 #
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。					
a. a.	Indications for use If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated. 使用指征 如果受试设备与基准设备在指征和预期用途方面没有差异，应明确说明。	☐	☐		
b. b.	Technology, including technical specifications, features, materials, and principles of operation Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation. FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness. 技术，包括技术规格、特性、材料和操作原理 技术特性的示例包括但不限于设计、特性、材料、能源来源和操作原理。 FDA 建议使用表格格式来比较技术特性。与对照设备相同的任何特性应明确说明。应识别技术特性的差异，并提供理由说明这些差异为何不会引发安全性和有效性方面的不同问题。	☐	☐		
	Comments: 评论：				

D.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable) 拟用标签（另请参阅适用的《联邦法规》第 21 编第 801 部分和第 809 部分的相关内容）						
	18.	Submission includes proposed package labels and labeling (e.g. instructions for use,package insert,operator's manual). 提交材料包括拟议的包装标签和标签说明（例如，使用说明、药品说明书、操作手册）。		☐	☐		
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k)Summary (if 510(k) Summary provided). 使用适应症在标签中予以说明，且与使用适应症表格以及 510（k）总结（若已提供 510（k）总结）中的内容一致。	☐	☐		
		b.	Labeling includes: – Statements of conditions,purposes or uses for which the device is intended (e.g.,hazards,warnings, precautions,contraindications)(21 CFR 801.5) **AND** – Includes adequate directions for use (see 21 CFR 801.5) **OR** – Submission states that device qualifies for exemption per 21 CFR 801 Subpart D 标签内容包括： – 关于器械预期使用的条件、目的或用途的说明（例如，危害、警告、注意事项、禁忌证）（《联邦法规》第 21 编第 801.5 条），并且 – 包含足够的使用说明（见《联邦法规》第 21 编第 801.5 条），或者 – 提交材料中声明该器械符合《联邦法规》第 21 编第 801 部分 D 子部分规定的豁免条件。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
	Comments: 评论：			
19. 19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1). 标签包括制造商、包装商或分销商的名称和营业地点（21 CFR 801.1）。	☐	☐		
	Comments: 评论：				
20. 20.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). Select " N/A " if not indicated for prescription use. 标签包括处方声明（见 21 CFR 801.109(b)(1)）或仅限处方符号（另见 FD&C 法第 502(a)节和 FDA 的最终规则“标签中的符号使用”（81 FR 38911），可在 https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling 获取）。如果未指明用于处方使用，请选择“ N/A ”。	☐	☐	☐	
	Comments: 评论：				
21. 21.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. If " N/A " is selected, parts a and b below are omitted from the checklist. 该设备具有针对特定设备的指导文件、特殊控制和/或适用于该设备的特定分类法规中的标签要求。 如果选择“N/A”，则下面的部分a和b将从清单中省略。	☐		☐	
a. a.	The submission addresses labeling recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select " N/A " if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的标签建议，或者 提交提供了一种替代方	☐	☐	☐	

		提交内容涉及设备特定指导中概述的标签建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何省略信息或上述任何替代方法的理由，请选择“否”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。						N/A 不适用	*Page # *页面#
		b. b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的标签信息。 或者 提交使用替代缓解措施，并提供理由说明为何替代措施提供了等同的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括对任何省略信息或上述任何替代方法的理由，请选择“否”。请注意，缓解措施的处理 adequacy 应在实质性审查中进行评估。	Yes ☐	No ☐	☐	
			Comments: 评论：				
	22. 22.		device is an in vitro diagnostic device, provided labeling des all applicable information required per 21 CFR 809.10. " N/A " if not an in vitro diagnostic device. 设备是体外诊断设备，提供的标签包含根据 21 CFR 809.10 要求的所有适用信息。 "N/A" 如果不是体外诊断设备。	☐	☐	☐	
			ment: 这份清单评估医疗器械 510(k)提交的完整性。它验证了设备描述、实质等效性讨论和标签信息的包含。还检查了与相关 FDA 法规和指导方针的合规性				
E. E.			o diagnostic (IVD) device and sterilization is not applicable, A." The criteria in this section will be omitted from the " N/A " is selected. 如果选择了“N/A”，则本节中的标准将被省略，A。“诊断（IVD）设备和灭菌不适用。”			☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Submission states that the device and/or accessories, if applicable, are: (one of the below must be checked) Provided sterile, intended to be single-use Requires processing during its use-life Non-sterile when used (and no processing required) Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) Sterility status not needed for this device (e.g., software-only device) Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist. If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No." The "Requires processing during its use-life" option refers to devices falling into one of the four categories below: - Supplied sterile and requires reprocessing prior to subsequent patient use - Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use - Reusable medical device (single-user) reprocessed between each use - Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information. 提交声明设备和/或配件（如适用）为：（以下选项中必须勾选一个） 提供无菌，旨在单次使用 在使用期间需要处理 使用时为非无菌（且不需要处理） 未提供设备的无菌状态信息（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要无菌状态（例如，仅软件设备） 需要无菌状态或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“使用时为非无菌”或“未提供且不需要”，则下面与无菌相关的标准将从清单中省略。 如果未提供无菌状态信息，并且该信息是必要的或需求不明确，请选择“否”。 “在使用期间需要处理”选项指的是以下四类设备： - 提供无菌并在后续患者使用前需要重新处理 - 提供非无菌并要求用户在初次使用前处理设备，以及在每次使用后重新处理设备 - 可重复使用的医疗设备（单用户）在每次使用之间重新处理 - 初次提供给用户时为非无菌的单次使用医疗设备，并要求用户在使用前处理设备 有关更多信息，请参阅 FDA 指导文件“医疗设备在医疗保健环境中的重新处理：验证方法和标签”，可在 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling 获取。	☐			
Comments: 评论：				
23. Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

	23. 清洁及后续消毒或灭菌信息需求的评估。				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is

如果项目存在，请勾选“是”，如果不需要，请勾选“不适用”，如果需要，请勾选“否”

not included but needed.

未包含但需要。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
	f. f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). Select "N/A" if not labeled "non-pyrogenic." 对于标记为“无热源”的产品，需描述用于做出该判断的方法（例如，柳虫血细胞溶解液 [LAL]）。 如果未标记为“无热源”，请选择“N/A”。	☐	☐	☐	
Comments: 评论：						
25. 25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: Select " N/A " if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below. 如果设备和/或配件（如适用）是可重复使用的或最终用户消毒或灭菌的： 如果设备或配件的任何部分都不是可重复使用的或最终用户消毒或灭菌的，请选择“N/A”，否则请完成下面的 a-d。			☐		
	a. a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization. 每个设备和/或配件的标签中提供了清洁方法（如适用）。 如果不可重复使用且在消毒或灭菌之前不需要清洁，请选择“N/A”。	☐	☐	☐	
	b. b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. Select " N/A " if not disinfected (i.e., undergoes terminal sterilization) prior to use. 每个设备和/或配件的标签中提供了消毒方法（如适用）。 如果在使用前未进行消毒（即，经过终末灭菌），请选择“N/A”。	☐	☐	☐	
	c. c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. Select " N/A " if not sterilized (i.e., undergoes disinfection) prior to use. 每个设备和/或配件的标签中提供了灭菌方法（如适用）。 如果在使用前未进行灭菌（即进行消毒），请选择“N/A”。	☐	☐	☐	

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果该项内容存在，请勾选 “是”；如果该项内容不需要，请勾选 “不适用（N/A）” ；如果该项内容缺失但又是必需的，请勾选 “否”。 * 随提交材料一并提交此清单的提交者，应标明所要求信息所在的页码。如果需要额外的空间来注明支持性信息的位置，请在相应项目的注释部分进行说明。					Yes 是	No 否	N/A 不适用	*Page# 页码
		d.	Device types in this submission are listed in the Federal Register (FR)Notice entitled"Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice,available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable) Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection.Select "N/A"if the device type in the submission is not included in the Reprocessing FR Notice 本次提交材料中的器械类型列于《联邦纪事》（FR）公告，标题为《某些可重复使用医疗器械上市前通知的经验证使用说明和验证数据要求》（再处理《联邦纪事》公告，可通过 https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable获取）。 再处理《联邦纪事》公告中所确定的器械类型指的是那些更有可能发生微生物传播且存在高感染风险的器械。如果提交材料中的器械类型未包含在再处理《联邦纪事》公告中，请选择 “不适用（N/A）”。		☐		☐	
			i.	If device types in this submission are included in the Reprocessing FR Notice,the submission includes protocols and test reports for validating the reprocessing instructions. Select"N/A"if the device type in the submission is not included in the Reprocessing FR Notice. 如果本次提交材料中的器械类型包含在再处理《联邦纪事》公告中，提交材料应包括用于验证再处理说明的方案和测试报告。 如果提交材料中的器械类型未包含在再处理《联邦纪事》公告中，请选择 “不适用（N/A）”。	☐	☐	☐	
			Comments: 评论：					
	26.	The device has a device-specific guidance document,special controls,and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device If "N/A"is selected,parts a and b below are omitted from the checklist. 该器械有一份针对该器械的指导文件、特殊控制措施，和 / 或在针对该器械的特定分类法规中有关于无菌和 / 或再处理的要求，且这些内容适用于所涉及的器械。			☐		☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
		a. a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的无菌和/或再处理建议。 或者 提交提供了旨在满足适用的法定和/或监管标准的替代方法。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“No”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。	☐	☐	☐	
		b. b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的无菌和/或再处理信息。 或者 提交使用替代缓解措施，并提供理由说明为何替代措施提供了等效的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“否”。请注意，如何处理这些缓解措施的充分性应在实质性审查中进行评估。	☐	☐	☐	
			Comments: 评论：				
F. F.	She 她	Lif 生命					
	27.		posed shelf life/ expiration date stated ement that shelf-life is not applicable because of low lihood of time-dependent product degradation.				

	27.		提出的保质期/过期日期声明 声明由于产品降解的时间依赖性低，因此保质期不适用。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
		Comments: 评论：				
	28. 28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. Select " N/A " if the device is not provided sterile. 对于无菌设备，提交包括用于建立设备包装将在整个提议的保质期内保持无菌屏障的方法摘要。 如果设备未提供无菌，请选择“N/A”。	☐	☐	☐	
		Comments: 评论：				
	29. 29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH , osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period. 提交包括用于确认设备性能在整个提议的保质期内保持的总结方法（例如，机械性能、涂层完整性、pH 值、渗透压等）。 或者 说明为什么不需要性能数据来确认设备性能特征在保质期内的维护。	☐	☐	☐	
		Comments: 评论：				
G. G.		Biocompatibility If an in vitro diagnostic (IVD) device, select " N/A." The criteria in this section will be omitted from the checklist if " N/A " is selected. 生物相容性 如果是体外诊断（IVD）设备，请选择“N/A”。如果选择“N/A”，本节中的标准将从清单中省略。			☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Submission states that there: (one of the below must be checked) Are direct or indirect tissue-contacting components Are no direct or indirect tissue-contacting components Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) Tissue contact information not needed for this device (e.g., softwareonly device) Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "are no" or "not provided and not needed" is selected, the biocompatibilityrelated criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissuecontacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue. 提交声明如下：（以下选项中必须勾选一个） 有直接或间接接触组织的组件 没有直接或间接接触组织的组件 设备的组织接触状态信息未提供（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要组织接触信息（例如，仅软件设备） 需要组织接触信息或需要不明确 此信息将决定是否以及需要何种类型的额外信息以进行实质等效性判断。 如果选择“没有”或“未提供且不需要”，则下面与生物相容性相关的标准将从清单中省略。如果未提供组织接触状态的信息，并且需要接触信息或其接触状态不明确，请选择“否”。 直接接触组织的设备的一个例子是使用过程中与组织直接接触的植入物。间接接触组织的设备的一个例子是液体在通过未与组织直接接触的设备/设备组件后进入体内。	☐			
Comments: 评论：				
30. 30.	Submission i device compo associated ma including ide 提交 i 设备组成相关 ma，包括 ide	☐	☐		
Comments: 评论：				
31. 31.	Submission i contacting, le device compo 提交我联系，设备组成	☐	☐		
Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
	32. 32.	For a biocompatibility assessment of tissue-contacting components, submission includes: - Each relevant endpoint for the device (as identified in devicespecific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, '" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate). 对于接触组织的组件的生物相容性评估，提交包括： - 设备的每个相关终点（如设备特定指导或 FDA 指导文件“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 A 中所识别的），已得到解决。 - 对于进行的任何测试，测试方案（包括测试物品的识别和描述，包括测试物品是否为最终成品设备，使用“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 F 中推荐的方法，以及通过/不通过标准），以及结果分析（包括适当时的数据点和统计分析的表格），如指导文件“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 E 中所述，为每个完成的测试提供。 或者 一份声明，说明不需要进行生物相容性测试，并提供考虑所有相关终点的理由（例如，材料和制造/加工与对照品相同）。	☐	☐		
		Comments: 评论：				
H. H.	Soft 软					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	No 不	N/A 不适用	*Page # *页面#
Submission states that the device: (one of the below must be checked) Does contain software/firmware Does not contain software/firmware Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) Software/firmware information not needed for this device (e.g., surgical suture, condom) Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No." 提交声明该设备：（以下选项中必须勾选一个） 包含软件/固件 不包含软件/固件 未提供设备是否包含软件/固件的信息 （如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要软件/固件信息（例如，外科缝合线，避孕套） 该设备需要软件/固件信息或需求不明确 此信息将决定是否以及需要何种类型的额外信息以进行实质等效性判断。 如果选择“未包含”或“未提供且不需要”，则下面与软件相关的标准将从清单中省略。如果未提供软件信息，并且该信息是必要的或需求不明确，请选择“否”。	☐		

Comments:

评论：

	33.	Submission includes a statement of software level of concern and rationale for the software level of concern 提交材料包含一份关于软件关注等级的声明，以及确定该软件关注等级的理由	☐	☐		
		Comments: 评论：				
	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device. 根据提交者所确定的关注等级，提供所有适用的软件文档，相关要求见《医疗器械所含软件上市前提交内容指南》（可通过 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices获取）；或者，提交材料包含相关信息，用以证明提交者已通过替代方法满足了适用的法定或监管标准（即，提交者已确定了一种替代方法并说明了理由）。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。			No 不	N/A 不适用	*Page # *页面#
	Comments: 评论：				
I. 我。	Cybersecurity 网络安全				
	Submission states that the device: (one of the below must be checked) Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) Does not contain external interfaces as described above Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) Cybersecurity information not needed for this device (e.g., surgical suture, condom) Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No." 提交声明该设备：（以下选项中必须勾选一个）包含任何外部有线和/或无线通信接口（有线：USB、以太网、SD、CD、RGA 等；无线：Wi-Fi、蓝牙、RF、感应、云等）不包含上述描述的外部接口未提供设备是否具有外部接口的信息（如果勾选此框，请同时勾选以下两个框中的一个）该设备不需要网络安全信息（例如，外科缝合线、避孕套）需要网络安全信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“未包含”或“未提供且不需要”，则下面的网络安全标准将从检查清单中省略。如果未提供网络安全信息，并且该信息是必要的或需求不明确，请选择“否”。		☐		
	35. 35.	All applicable docume described in "Guidanc Submissions for Mana Devices," available at information/search-fda submissions-managem OR Submission includes i has otherwise met the through an alternative an alternate approach 所有适用的文件均在“管理设备提交指南”中描述，您可以在信息/搜索-FDA 提交-管理中找到。 或者 提交包括信息，或者通过替代方法满足要求	☐		
		Comments: 评论：			
J. J.		rical Safety and EMC 电气安全和电磁兼容性			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Electrical Safety: Submission states that the device: (one of the below must be checked) Does require electrical safety evaluation Does not require electrical safety evaluation Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) Electrical safety information not needed for this device (e.g., surgical suture, condom) Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No." 电气安全： 提交声明该设备：（以下选项中必须勾选一个）需要电气安全评估 不需要电气安全评估 是否需要电气安全评估的信息未提供（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要电气安全信息（例如，外科缝合线，避孕套） 需要电气安全信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“无需”或“未提供且不需要”，则下面的电气安全标准将从清单中省略。如果未提供电气安全信息，并且需要该信息或对该信息的需求不明确，请选择“否”。		☐		
36. 36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale). 提交包括电气安全评估（例如，按照 IEC 60601-1 或等效的 FDA 认可标准，如果适用，还包括特定设备标准）。 或者 提交包括使用未获得 FDA 认可的方法或标准进行的电气安全评估，并且提交包括信息以证明提交者通过这种替代方法满足了适用的法定或监管标准（即，提交者已识别出替代方法或标准并提供了理由）。	☐	☐		
	Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
EMC: Submission states that the device: (one of the below must be checked) Does require EMC evaluation Does not require EMC evaluation Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) EMC information not needed for this device (e.g., surgical suture, condom) EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No." EMC： 提交声明该设备：（以下选项中必须勾选一个） 需要进行 EMC 评估 不需要进行 EMC 评估 未提供设备是否需要 EMC 评估的信息（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要 EMC 信息（例如，外科缝合线，避孕套） 需要 EMC 信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。如果选择“无需”或“未提供且不需要”，则下面的 EMC 标准将从清单中省略。如果未提供 EMC 信息，并且需要该信息或对该信息的需求不明确，请选择“否”。		☐		
Comments: 评论：				
37. 37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDArecognized standard and if applicable, a device-specific standard). OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale). 提交包括电磁兼容性评估（例如，按照 IEC 60601-1-2 或等效的 FDA 认可标准，如果适用，还包括特定设备标准）。 或者 提交包括使用非 FDA 认可的方法或标准进行的电磁兼容性评估，并且提交包括信息以证明提交者通过这种替代方法满足了适用的法定或监管标准（即，提交者已识别出替代方法或标准并提供了理由）。	☐	☐		
Comments: 评论：				

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选 “是”；如果不需要该项目，请勾选 “不适用”；如果该项目未包含但有需要，请勾选 “否”。 提交材料时附上本清单的提交者应标明所要求信息所在的页码。如果需要额外空间来标明佐证信息的位置，可以在某一要素对应的评论栏中进行说明。			Yes 是	No 否	N/A 不适用	*Page# 页码
K.	**Performance Data General** If an in vitro diagnostic(IVD)device,select "N/A."The criteria in this section will be omitted from the checklist if "NA"is selected. Performance data criteria relating to IVD devices is addressed in Section L. 一般性能数据 如果是体外诊断（IVD）设备，请选择 “不适用（N/A）”。如果选择了 “不适用（N/A）”，本部分中的标准将从清单中省略。 与体外诊断（IVD）设备相关的性能数据标准在 L 部分中阐述。					☐	
	Comments: 评论：						
	38.	Summaries of the non-clinical laboratory studies and full test reports*are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions,"available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized,submission of a full test report may not be necessary.Refer to 9a.See FDA's guidance"Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,"available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. Select "N/A"if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.已提供非临床实验室研究的摘要和完整测试报告 *。 * 摘要和完整测试报告的内容建议可在 FDA 的指南《上市前提交文件中非临床台架性能测试信息的推荐内容和格式》中找到，该指南网址为 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket 。 如果提交者选择声明符合 FDA 已认可的自愿性共识标准，可能无需提交完整的测试报告。请参阅 9a。 可查看 FDA 的指南《医疗器械上市前提交文件中自愿性共识标准的恰当使用》，网址为https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices 。 如果提交文件恰当地未包含性能数据，或者不存在无合格声明的已完成测试，则选择 “不适用（N/A）”。		☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence(e.g.,comparison to predicate device testing, dimensional analysis,etc.). Select "N/A"if the submission does not include performance data. 提交材料包含对每项测试所产生的数据如何支持实质等同性判定的解释（例如，与对比器械测试的对比、尺寸分析等）。 如果提交材料不包含性能数据，则选择 “不适用（N/A）”。	☐	☐	☐	
	Comments: 评论：						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

提交者在提交时应附上清单并进行识别

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

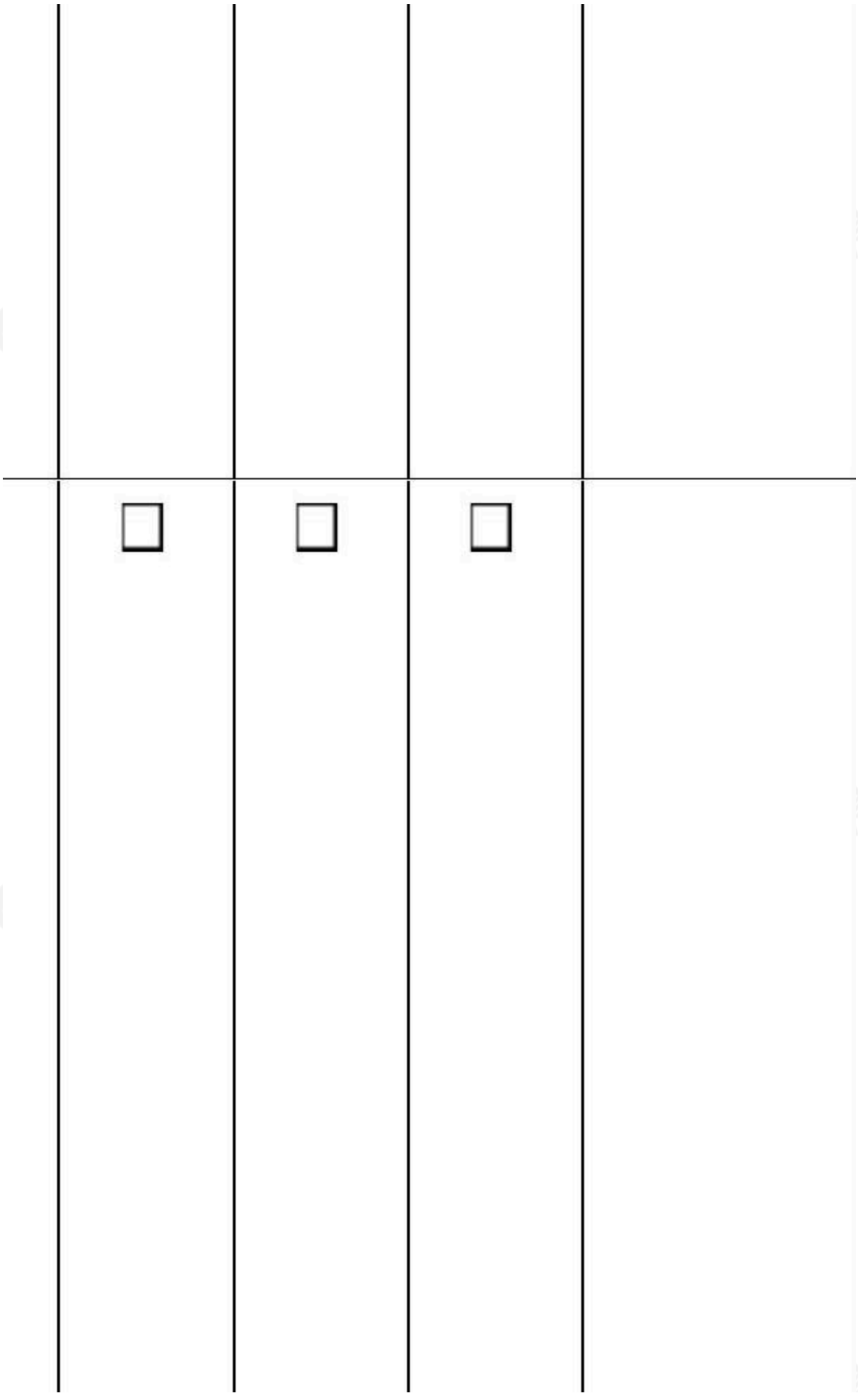
comments section for an element if additional space is needed to identify

如果需要额外空间来识别某个元素，请在评论部分填写

the location of supporting information.

支持信息的位置。

Yes 是	No 否	N/A 不适用
☐		☐
☐	☐	☐



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页码#
40. 40.		erature is referenced in the submission, submission des: " " N/A " if the submission does not reference literature. If " is selected, parts a and b below are omitted from the klist. that the applicability of the referenced article to support a tantial equivalence finding should be assessed during the antive review; only the presence of a discussion is required pport acceptance. 在提交中引用了文献，提交描述：“如果提交未引用文献，则为“N/A”。如果选择“”，则省略下面的部分a和b。 在主动审查过程中，应评估引用文章对支持实质等效性发现的适用性；仅需存在讨论即可支持接受。			☐	
	a. a.	Legible reprints or a summary of each article. 每篇文章的清晰复印件或摘要。	☐	☐		
	b. b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate. 讨论每篇文章如何适用于支持目标设备与对照设备的实质等效性。	☐	☐		
		Comments: 评论：				
41. 41.		ach completed animal study, the submission provides the wing: " " N/A " if no animal study was conducted. If " N/A " is ted, parts a-c below are omitted from the checklist. Note his section does not address biocompatibility evaluations, h are assessed in Section G of the checklist. 每个完成的动物研究，提交提供以下内容：“” N/A “如果没有进行动物研究。如果“ N/A ”被引用，则下面的部分 a-c 将从清单中省略。请注意，本节不涉及生物相容性评估，这在清单的第 G 节中进行评估。			☐	
	a. a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120 提交包括一份研究方案，其中包含 21 CFR 58.120 中列出的所有要素。	☐	☐		
	b. b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185 提交包括最终研究报告，其中包含 21 CFR 58.185 中列出的所有要素。	☐	☐		
	c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				

	c.	提交包含一份声明，表明研究是按照适用的 GLP 法规（21 CFR 第 58 部分）进行的，或者如果研究未按照 GLP 法规进行，提交解释了为何不合规不会影响提供的研究数据的有效性，以支持实质等同性的判断。	☐	☐		
		Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。				Yes 是的	No 不	N/A 不适用	*Page # *页面 #
L. L.	Performance Characteristics - In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12)) 性能特征 - 仅适用于体外诊断设备（另见 21 CFR 809.10(b)(12)）						
	Submission indicates that device: (one of the below must be checked) Is an in vitro diagnostic device Is not an in vitro diagnostic device If "is not" is selected, the performance data-related criteria below are omitted from the checklist. 提交表示设备：（以下之一必须被勾选）是体外诊断设备 不是体外诊断设备 如果选择“不是”，则下面与性能数据相关的标准将从清单中省略。						
	42. 42.		ission includes the following studies, as appropriate for the type, including associated protocol descriptions, study s and line data: 使命包括以下研究，具体取决于类型，包括相关的协议描述、研究和线数据：				
		a. a.	Precision/reproducibility 精确度/可重复性	☐	☐	☐	
		b. b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff). 准确性（包括适当的线性；校准物或检测的可追溯性；校准物和/或检测稳定性协议及接受标准；检测截止值；方法比较或与临床结果的比较；基质比较；以及临床参考范围或截止值）。	☐	☐	☐	
		c. c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type). 灵敏度（检测限，LoB，LoD，LoQ，适用于设备类型时）。	☐	☐	☐	
		d. d.	Analytical specificity 分析特异性	☐	☐	☐	
			Comments: 评论：				
	43.		device has a device-specific guidance document, special rols, and/or requirement in a device-specific classification ation regarding performance data that is applicable to the ect device.				

	4 3.		V/A" is selected, parts a and b below are omitted from the klist. 设备具有特定于设备的指导文件、特殊角色和/或在特定于设备的分类中关于适用于该设备的性能数据的要求。 如果选择了“V/A”，则下面的部分 a 和 b 将从清单中省略。	☐	☐	☐	

		Yes 是的	No 不	N/A 不适用	*Page # *页面#
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。					
a. a.	The submission addresses performance data recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的性能数据建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息的理由或上述任何替代方法，请选择“No”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。	☐	☐	☐	
b. b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的性能数据。 或者 提交使用替代缓解措施，并提供理由说明这些替代措施为何提供等效的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“否”。请注意，如何处理这些缓解措施的充分性应在实质性审查期间进行评估。	☐	☐	☐	
	Comments: 评论：				

Checklist for Traditional 510(k)s

传统 510(k)检查清单

The following information is not intended to serve as a comprehensive review. FDA recommends that the submitter include this completed checklist as part of the application.

以下信息并不旨在作为全面审查。FDA 建议提交者将此已完成的检查清单作为申请的一部分。

Preliminary Questions

初步问题

> Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)
>
> 阴影框中的答案表示需要与指定中心顾问进行咨询。（本节中勾选的框代表 FDA 在行政审查时对这些问题的初步评估。）

1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a **510(k)** ?

   该产品是设备（根据 FD&C 法第 201(h)节）还是组合产品（根据 21 CFR 3.2(e)）且其组成部分为设备，需在**510(k)**中进行审查吗？

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果它似乎不是设备（根据 FD&C 法案第 201(h)节）或这样的组合产品（根据 21 CFR 3.2(e)），或者您不确定，请咨询 CDRH 产品管辖官员或 CBER 产品管辖官员以确定适当的行动，并通知管理层。在下面的评论部分提供产品管辖官员的决定/建议/行动的摘要。

If the product does not appear to be a device or such a combination product, mark "No."

如果该产品似乎不是设备或此类组合产品，请标记“否”。

Comments:

评论：

2. Is the submission with the appropriate Center?

2. 提交是否在适当的中心？

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果产品是设备或包含设备成分的组合产品，它是否需要由接收提交的中心进行审查？如果您认为提交不在适当的中心，或者您不确定，请咨询 CDRH 产品管辖官或 CBER 产品管辖官，以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

If submission should not be reviewed by your Center mark "No."

如果提交不应由您的中心审核，请标记为“否”。

Comments:

评论：

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

   如果已提交针对该设备或包含设备成分的组合产品的指定请求（RFD），并分配给您的中心，请识别 RFD 编号并确认以下内容：

   (a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?

   (a) 该设备或组合产品是否与 RFD 提交中呈现的相同（例如，设计、配方）？

   (b) Are the indications for use for the device or combination product identified in the $510(k)$ the same as those identified in the RFD submission?

   (b) 设备或组合产品的使用指示在 $510(k)$ 中是否与 RFD 提交中识别的相同？

If you believe the product or the indications presented in the $510(k)$ have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果您认为在$510(k)$中呈现的产品或适应症与 RFD 有所变化，或者您不确定，请咨询 CDRH 产品管辖官或 CBER 产品管辖官，以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."

如果上述任一问题的答案是否定的，请标记为“否”。如果没有 RFD，请标记为“N/A”。

Comments:

评论：

4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act?

该提交是否为一种组合产品，其中包含作为组成部分的药物，该药物具有与根据 FD&C 法第 503(g)(5)(C)(ii)-(v)节获得专 exclusivity 的批准药物相同的活性成分？

If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.

如果“是”，请联系 CDRH 产品管辖官或 CBER 产品管辖官以确定适当的行动并通知您的管理层。在下面的评论部分提供产品管辖官的决定/建议/行动的摘要。

Comments:

评论：

5. Is this device type eligible for a **510(k)** submission?

该设备类型是否符合 **510(k)** 提交的资格？

If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."

如果 510(k)似乎不合适（例如，属于 III 类且需要 PMA，或属于 I 类或 II 类且免于 510(k)），请在接受审查期间咨询相关的 CDRH 或 CBER 工作人员，提供与他们讨论的摘要，并在下面的评论部分中指明他们的建议/行动。如果 510(k)不是适当的监管提交，请标记为“否”。

Comments:

评论：

6. Is there a pending PMA for the same device with the same indications for use?

6. 是否有针对相同适应症的相同设备的待审 PMAs？

If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.

如果“是”，请咨询您的管理层和 CDRH 产品评估与质量办公室/监管项目办公室/监管项目部 1（提交支持）（OPE

Q/ORP/DRP1）或适当的 CBER 工作人员，以确定适当的行动。

Comments:

评论：

7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

   如果已提交临床研究，提交者是否受到申请完整性政策（AIP）的约束？

If "Yes," consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action.

如果“是”，请咨询 CDRH 产品评估与质量办公室/临床证据与分析办公室/临床科学与质量部（OPEQ/OCEA/DCEA 1）或 CBER 合规与生物制品质量办公室/检查与监测部/生物研究监测分支（OCBQ/DIS/BMB），以确定适当的行动，提供与他们讨论的摘要，并指明他们的建议/行动。

If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.

如果没有提交临床研究，请标记为“无”。请在 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list 上查看 AIP 列表。

Comments:

评论：

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.

  如果对 1 或 2 的回答似乎是“否”，则停止对 510(k)的审查，并联系 CDRH 产品管辖官或 CBER 产品管辖官。

- If the answer to 3 a or 3 b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.

  如果对 3 a 或 3 b 的回答似乎是“否”，则停止审查并联系 CDRH 产品管辖官或 CBER 产品管辖官。

- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.

  如果第 4 项的答案是“是”，请联系 CDRH 产品管辖官或 CBER 产品管辖官，提供与他们讨论的摘要，并说明他们的建议/行动。

- If the answer to 5 is " No ", the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or

  如果第 5 项的答案是“否”，主审查员应咨询部门管理层和其他中心资源，以确定适当的行动。请注意，对于明显不符合510(k）提交条件的设备（例如需要 PMA 的 III 类设备类型或

class I/II and $510(k)$ exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

对于 I/II 类和$510(k)$豁免设备，这可能被视为拒绝接受提交的依据。对于触及豁免限制的 I/II 类、510(k)豁免设备提交的 510(k)不会基于此理由被拒绝。

- If the answer to 6 is "Yes," then stop review of the $510(k)$, contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.

如果第 6 问的答案是“是”，则停止对$510(k)$的审查，联系 CDRH/OPEQ/ORP/DRP1 或适当的 CBER 工作人员。

- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

如果第 7 问的答案是“是”，请联系 CDRH/OPEQ/OCEA/DCEA1 或 CBER/OCBQ/DIS/BMB，提供与 DCEA1 或 BMB 工作人员讨论的摘要，并说明他们的建议/行动。

Organizational Elements

组织元素

Failure to include these items should not result in an RTA designation.

未能包含这些项目不应导致 RTA 标记。

		Yes 是的	No 不	*Page # *页面#
	*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. *提交者在提交材料时应附上清单，并标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。			
1. 1.	Submission contains a Table of Contents. 提交包含目录。	☐	☐	
2. 2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.). 每个部分都有标签（例如，标头或标签指定设备描述部分、标签部分等）。	☐	☐	
3. 3.	All pages of the submission are numbered. All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...). 提交的所有页面都应编号。 所有页面应以可以通过页码引用信息的方式编号。这可以通过对整个提交进行连续编号，或对某个部分内的页面进行编号（例如，12-1，12-2...）来完成。	☐	☐	
4. 4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) If type of 510(k) is not designated, review as a Traditional 510(k). 510(k)的类型已确定（即，传统、简化或特殊）。如果未指定510(k)的类型，请作为传统 510(k)进行审查。	☐	☐	

Comments:

评论：

Elements of a Complete Submission (RTA Items)

完整提交的要素（**RTA** 项目）

(21 CFR 807.87 unless otherwise indicated)

（**21 CFR 807.87**，除非另有说明）

Submission should be designated RTA if not addressed.

如果未解决，提交应标记为 **RTA**。

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.

  任何“否”回答将导致“拒绝接受”的决定；然而，FDA 工作人员有权决定缺失的项目是否需要，以确保提交在行政上是完整的，从而允许提交被接受，或者在 RTA 审查期间与提交者互动请求缺失的检查清单项目。

- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

  每个检查表上的元素都应在提交中得到处理。提交者可以为任何被认为不适用的标准提供省略的理由。如果提供了理由，则该标准被视为存在（是）。在审查提交时，将考虑对理由的评估。

  Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

  如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 随提交材料一并附上本清单的提交者应标明所要求信息所在的页码。如果需要额外的空间来标明佐证信息的位置，可在某一要素对应的评论栏中进行说明。			Yes 是	No 否	N/A 不适用	*Page# 页码
A.	Administrative管理方面					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) 所有用于支持该提交文件的内容均以英文书写（包括测试报告、文献文章等的译文）。	☐	☐		
		Comments: 评论：				
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download): 提交材料需标明以下内容（美国食品药品监督管理局（FDA）建议使用器械和放射健康中心（CDRH）的上市前审评提交文件封面表格（3514 表格，可从https://www.fda.gov/media/72421/download下载））：				
		a. Device trade/proprietary name 器械的商品名称 / 专有名称	☐	☐		
		b. Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion 器械类别和专业评审小组（信息）；或者 分类法规（信息）；或者 声明该器械尚未分类，并说明得出该结论的理由	☐	☐		
		Comments: 评论：				
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling) See recommended format (https:// www.fda.gov/media/86323/download). 提交材料包含一份带有处方药（Rx）和 / 或非处方药（OTC）标识的适用范围声明（另见《美国联邦法规》第 21 编第 801.109 条，以及美国食品药品监督管理局（FDA）的最终规定《标签中符号的使用》（《联邦纪事》第 81 卷第 38911 页），可从https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling获取）。 见推荐格式（https://www.fda.gov/media/86323/download）。	☐	☐		
		Comments: 评论：				
	4.	Submission contains a 510(k) Summary or 510(k) Statement. Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review. 提交材料包含一份 510（k）总结或 510（k）声明。关于 510（k）总结和声明的内容，分别参阅《美国联邦法规》第 21 编第 807.92 条和第 21 编第 807.93 条。内容的充分性将在实质性审评期间进行评估。	☐	☐		
		Comments: 评论：				

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选 “是”；如果不需要该项目，请勾选 “不适用（N/A）”；如果该项目未包含但又是必需的，请勾选 “否”。 随提交材料一并附上本清单的提交者应标明所要求信息所在的页码。如果需要额外空间来标明佐证信息的位置，请在某一要素对应的评论栏中说明。				Yes 是	No 否	N/A 不适用	*Page# 页码
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(1) See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement). 提交材料包含一份符合《美国联邦法规》第 21 编第 807.87 (1) 条规定的真实性与准确性声明。 请参阅推荐格式（https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement）。			☐	☐		
		Comments: 评论：						
	6.	Submission is a class III510(k)Device. Select "N/A"only if submission is not a class II 510(k). 提交的是三类 510 (k) 医疗器械。 仅当提交的不是二类 510 (k) 医疗器械时，才选择 “不适用（N/A）”。			☐		☐	
		a.	Contains class II Summary and Certification per 21 CFR 807.87(k). See recommended content(https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary).Select "N/A"only ifsubmission is not a class II510(k) 包含符合《美国联邦法规》第 21 编第 807.87 (k) 条规定的二类（医疗器械）总结和证明文件。 请参阅推荐内容（https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary）。仅当提交的不是二类 510 (k)（医疗器械）时，才选择 “不适用（N/A）”。	☐	☐	☐	
		Comments: 评论：						
	7.	Submission contains clinical data. Select"N/A"if the submission does not contain clinical data.If "N/A"is selected,parts a,b,and c below are omitted from the checklist. 提交材料包含临床数据。 如果提交材料不包含临床数据，则选择 “不适用（N/A）”。如果选择了 “不适用（N/A）”，以下的 a、b 和 c 部分将从清单中省略。			☐		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454,available at https://www.fda.gov/media/70465/download)or Disclosure (FDA Form 3455,available at https://www.fda.gov/media/69872/download)information for each covered clinical study included in the submission Select "N/A"if the submitted clinical data is not a "covered clinical study"as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-quidance-documents/financial-disclosure-clinical-investigators.提交材料包含针对所提交内容中纳入的每项受涵盖临床研究的已填写完整的财务认证（美国食品药品监督管理局（FDA）3454 表格，可从https://www.fda.gov/media/70465/download下载）或披露（FDA 3455 表格，可从https://www.fda.gov/media/69872/download下载）信息。 如果所提交的临床数据不属于题为《临床研究者的财务披露》指南（可从 https://www.fda.gov/regulatory-information/search-fda-quidance-documents/financial-disclosure-clinical-investigators获取该指南）中所定义的 “受涵盖临床研究”，则选择 “不适用（N/A）”。		☐	☐	

		Yes 是的	No 不	N/A 不适用	*Page # *页面#
	Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。				
b. b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manualsforms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j). 提交包括符合 ClinicalTrials.gov 数据银行要求的合规性认证（请参见 FDA 表格 3674，可在 https://www.fda.gov/about-fda/reports-manualsforms/forms 获取）（42 U.S.C. 282(j)(5)(B)），适用于提交中包含的每个相关设备临床试验。 如果提交的临床数据不是 FDAAA 第八章第 801(j)条款中定义的“适用设备临床试验”，请选择“N/A”。	☐	☐	☐	
c. c.	Statements of Compliance for Clinical Investigations Select " N/A " if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence. For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019. Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information. 临床研究合规声明 如果提交不包含任何来自研究的临床数据（如 21 CFR 812.3(h)所定义）以证明实质等效性，请选择“N/A”。 对于涉及美国（US）和美国以外（OUS）地点的多中心临床研究，部分（i）应针对美国地点进行处理，部分（ii）应针对美国以外地点进行处理。21 CFR 812.28 适用于 2019 年 2 月 21 日或之后招募第一名受试者的所有美国以外的临床研究。 有关更多信息，请参阅题为“接受临床数据以支持医疗器械申请和提交 - 常见问题”的指导文件，网址为 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked。	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交材料时应附上清单，并应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

			Yes 是的	No 不	N/A 不适用	*Page # *页面#
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。						
8. 8.		submission identifies prior submissions for the same device uded in the current submission (e.g., submission numbers for or not substantially equivalent [NSE] determination, prior ted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). s that there were no prior submissions for the subject ce. r submissions (or no prior submissions) for this device ld be included in Section F (prior related submissions) of CDRH Premarket Review Submission Cover Sheet form m 3514, available at s://www.fda.gov/media/72421/download). This information also be included in the Cover Letter (i.e., as a statement that were no prior submissions for the device or a listing of the ber(s) of the prior submissions). 提交识别当前提交中使用的相同设备的先前提交（例如，针对不实质等效[NSE]判定的提交编号，先前的 510(k)提交或撤回，Q-提交，IDE，PMA 等）。 确认该设备没有先前的提交。 r 提交（或没有先前提交）应包含在 CDRH 预市场审查提交封面表格m 3514 的 F 部分（先前相关提交）中，表格可在 s://www.fda.gov/media/72421/download 获取。该信息也应包含在封面信中（即，作为声明，表明该设备没有先前提交或列出先前提交的编号）。	☐	☐		
	a. a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review. Select " N/A " if the submitter states there were no prior submissions. 如果之前有提交，提交者已确定在当前提交中与该设备之前提交的实质等同性判定相关的任何问题是如何解决的。 为满足此标准，建议提交中包含一个单独的部分，列出之前的提交编号、FDA 反馈的副本（例如，信函、会议记录），以及说明在提交中如何或在哪里解决了这些之前的反馈。请注意，反馈解决的充分性将在实质审查期间进行评估。 如果提交者声明没有之前的提交，请选择“N/A”。	☐	☐	☐	
		Comments: 评论：				
9. 9.		submission utilizes voluntary consensus standard(s) (See on 514(c) of the FD&C Act). This includes both FDAgnized and non-recognized consensus standards. Select A" if the submission does not utilize voluntary consensus dards. 提交利用自愿共识标准（见 FD&C 法案第 514(c)条）。这包括 FDA 认可和未被认可的共识标准。如果提交不使用自愿共识标准，请选择“A”。	☐		☐	
	a. a.	The submission cites FDA-recognized voluntary consensus standard(s). 提交引用了 FDA 认可的自愿共识标准。	☐		☐	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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but
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*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交材料时应附上清单，并标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。				Yes 是的	No 不	N/A 不适用	*Page # *页面#
		a. a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act. 提交包括适当的专利声明或认证，以及提交者将根据需要发出通知的声明。请参见 FD&C 法案第 503(g)(5)(A)和(C)节。		☐	☐		
Comments: 评论：							
B. B.	Device Description 设备描述						
	12. 1 2.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. If " N/A " is selected, parts a and b below are omitted from the checklist. 该设备具有针对特定设备的指导文件、特殊控制和/或适用于该设备描述的特定设备分类法规中的要求，这些要求适用于所述设备。 如果选择“N/A”，则下面的部分a和b将从清单中省略。		☐		☐	
		a. a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select " N/A " if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的设备描述建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息的理由或上述任何替代方法，请选择“否”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。		☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

*提交者在提交材料时应标识包含清单

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

comments section for an element if additional space is needed to identify

如果需要额外空间来识别，请为一个元素添加评论部分

the location of supporting information.

支持信息的位置。

*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Yes 是的	No 不	N/A 不适用	* Page # * 页 #
☐	☐	☐ 是 否 不适用 * 页码 ☐ ☐ ☐	

Comments:

评论：

13. 13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling). 描述性信息在提交中是存在且一致的（例如，设备描述部分与标签中的设备描述一致）。	☐	☐		
14. 14.	Comments: The submission includes descriptive information for the device, including the following: 评论： 提交包括设备的描述性信息， 包括以下内容：				
a. A description of the principle of operation or mechanism of action for achieving the intended effect. 实现预期效果的操作原理或作用机制的描述。	☐	☐			
b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. 对拟议使用条件的描述，例如： 植入物的外科技术；使用的解剖位置； 用户界面；设备如何与其他设备交互； 以及/或设备如何与患者交互。	☐	☐			
c. A list and description of each device for which clearance is requested. Select 'N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc. 请求批准的每个设备的列表和描述。 如果只有一个设备或型号，请选择“N/A”。 “设备”可以指型号、部件编号、各种尺寸等。	☐	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

*提交者在提交材料时应标识包含清单

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

comments section for an element if additional space is needed to identify

如果需要额外空间来识别某个元素，请在评论部分填写

the location of supporting information.

支持信息的位置。

Yes 是的	No 不	N/A 不适用	∗ Page # ∗ 页 #
☐	☐ 是 否 不适用 ∗ 页码 ☐ ☐		

Comments:

评论：

15. 15.	Device is intended to be marketed with accessories and/or as part of a system. Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist. 设备旨在与配件和/或作为系统的一部分进行市场销售。 如果设备不打算与配件和/或作为系统的一部分进行市场销售，请选择“无”。如果选择“无”，则以下 a-c 部分将从清单中省略。	☐		☐	
a. Submission includes a list of all accessories to be marketed with the subject device. 提交包括与主题设备一起销售的所有配件清单。	☐	☐			
b. Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. Select 'N/A" if the accessory (ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications. 提交包括对每个附件的描述（如上述第 14a、14b 和 14d 项所述）。如果附件已被之前批准或免除，并且拟议的使用指示与已批准的指示一致，请选择“N/A”。	☐	☐	☐		
c. A 510(k) number is provided for each accessory that received a prior 510(k) clearance. AND 每个获得先前 510(k)批准的配件都提供一个 510(k)编号。	☐	☐			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. *提交者在提交材料时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
C. Substantial Equivalence Discussion C. 实质等同性讨论				
16. Submitter has identified a predicate device(s), including the following information: 16. 提交者已识别出一个或多个对照设备，包括以下信息：				
a. Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status). a. 提供了前驱设备标识符（例如，510(k)号、De Novo 号、重新分类的 PMA 号、分类法规参考，如果免除（例如，21 CFR 872.3710），或声明前驱设备是修订前设备）。 对于修订前设备，提供信息以记录修订前状态。 有关记录修订前状态的信息可在线获取（https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status）。	☐	☐		
b. The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing. b. 所识别的前提设备在整个提交中是一致的（例如，实质等同性部分中识别的前提设备与510(k)摘要中列出的设备（如适用）以及在比较性能测试中使用的设备相同）。	☐	☐		
Comments: 评论：				
17. Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], " available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics. 17. 提交包括对前体设备和主体设备的比较，以及讨论主体设备与前体设备之间的任何差异为何不影响安全性和有效性 [参见 FD&C 法案第 513(i)(1)(A)节和 21 CFR 807.87(f)]。 有关比较预期用途和技术特征的更多信息，请参阅 FDA 指导文				

		件“510(k)计划：评估上市前通知[510(k)]中的实质性等效性”，可在 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k 获取。				

		Yes 是的	No 不	N/A 不适用	*Page # *页面 #
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。					
a. a.	Indications for use If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated. 使用指征 如果受试设备与基准设备在指征和预期用途方面没有差异，应明确说明。	☐	☐		
b. b.	Technology, including technical specifications, features, materials, and principles of operation Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation. FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness. 技术，包括技术规格、特性、材料和操作原理 技术特性的示例包括但不限于设计、特性、材料、能源来源和操作原理。 FDA 建议使用表格格式来比较技术特性。与对照设备相同的任何特性应明确说明。应识别技术特性的差异，并提供理由说明这些差异为何不会引发安全性和有效性方面的不同问题。	☐	☐		
	Comments: 评论：				

D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)** **拟用标签（另请参阅适用的《美国联邦法规》第 21 编第 801 部分和第 809 部分）**						
	18.	Submission includes proposed package labels and labeling (e.g. instructions for use, package insert, operator's manual). 提交材料包括拟议的包装标签和标签说明（例如，使用说明、包装插页、操作手册）。		☐	☐		
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided). 适用范围在标签中予以说明，且与适用范围表格以及 510（k）总结（如果已提供 510（k）总结）中的内容一致。	☐	☐		
		b.	Labeling includes: – Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** – Includes adequate directions for use (see 21 CFR 801.5) **OR** – Submission states that device qualifies for exemption per 21 CFR 801 Subpart D 标签包含： – 关于器械预期使用的条件、目的或用途的说明（例如，危害、警告、注意事项、禁忌证）（《美国联邦法规》第 21 编第 801.5 条），并且 – 包含充分的使用说明（见《美国联邦法规》第 21 编第 801.5 条），或者 – 提交材料声明该器械符合《美国联邦法规》第 21 编第 801 部分 D 子部分规定的豁免条件。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
	Comments: 评论：			
19. 19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1). 标签包括制造商、包装商或分销商的名称和营业地点（21 CFR 801.1）。	☐	☐		
	Comments: 评论：				
20. 20.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). Select " N/A " if not indicated for prescription use. 标签包括处方声明（见 21 CFR 801.109(b)(1)）或仅限处方符号（另见 FD&C 法第 502(a)节和 FDA 的最终规则“标签中的符号使用”（81 FR 38911），可在 https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling 获取）。如果未指明用于处方使用，请选择“ N/A ”。	☐	☐	☐	
	Comments: 评论：				
21. 21.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. If " N/A " is selected, parts a and b below are omitted from the checklist. 该设备具有针对特定设备的指导文件、特殊控制和/或适用于该设备的特定分类法规中的标签要求。 如果选择“N/A”，则下面的部分a和b将从清单中省略。	☐		☐	
a. a.	The submission addresses labeling recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select " N/A " if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的标签建议，或者 提交提供了一种替代方	☐	☐	☐	

		提交内容涉及设备特定指导中概述的标签建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何省略信息或上述任何替代方法的理由，请选择“否”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。						N/A 不适用	*Page # *页面#
		b. b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的标签信息。 或者 提交使用替代缓解措施，并提供理由说明为何替代措施提供了等同的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括对任何省略信息或上述任何替代方法的理由，请选择“否”。请注意，缓解措施的处理 adequacy 应在实质性审查中进行评估。	Yes ☐	No ☐	☐	
			Comments: 评论：				
	22. 22.		device is an in vitro diagnostic device, provided labeling des all applicable information required per 21 CFR 809.10. " N/A " if not an in vitro diagnostic device. 设备是体外诊断设备，提供的标签包含根据 21 CFR 809.10 要求的所有适用信息。 "N/A" 如果不是体外诊断设备。	☐	☐	☐	
			ment: 这份清单评估医疗器械 510(k)提交的完整性。它验证了设备描述、实质等效性讨论和标签信息的包含。还检查了与相关 FDA 法规和指导方针的合规性				
E. E.			o diagnostic (IVD) device and sterilization is not applicable, A." The criteria in this section will be omitted from the " N/A " is selected. 如果选择了“N/A”，则本节中的标准将被省略，A。“诊断（IVD）设备和灭菌不适用。”			☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Submission states that the device and/or accessories, if applicable, are: (one of the below must be checked) Provided sterile, intended to be single-use Requires processing during its use-life Non-sterile when used (and no processing required) Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) Sterility status not needed for this device (e.g., software-only device) Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist. If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No." The "Requires processing during its use-life" option refers to devices falling into one of the four categories below: - Supplied sterile and requires reprocessing prior to subsequent patient use - Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use - Reusable medical device (single-user) reprocessed between each use - Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information. 提交声明设备和/或配件（如适用）为：（以下选项中必须勾选一个） 提供无菌，旨在单次使用 在使用期间需要处理 使用时为非无菌（且不需要处理） 未提供设备的无菌状态信息（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要无菌状态（例如，仅软件设备） 需要无菌状态或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“使用时为非无菌”或“未提供且不需要”，则下面与无菌相关的标准将从清单中省略。 如果未提供无菌状态信息，并且该信息是必要的或需求不明确，请选择“否”。 “在使用期间需要处理”选项指的是以下四类设备： - 提供无菌并在后续患者使用前需要重新处理 - 提供非无菌并要求用户在初次使用前处理设备，以及在每次使用后重新处理设备 - 可重复使用的医疗设备（单用户）在每次使用之间重新处理 - 初次提供给用户时为非无菌的单次使用医疗设备，并要求用户在使用前处理设备 有关更多信息，请参阅 FDA 指导文件“医疗设备在医疗保健环境中的重新处理：验证方法和标签”，可在 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling 获取。	☐			
Comments: 评论：				
23. Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

	23. 清洁及后续消毒或灭菌信息需求的评估。				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is

如果项目存在，请勾选“是”，如果不需要，请勾选“不适用”，如果需要，请勾选“否”

not included but needed.

未包含但需要。

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在某个元素的评论部分中使用。

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果未包含但需要，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
	f. f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). Select "N/A" if not labeled "non-pyrogenic." 对于标记为“无热源”的产品，需描述用于做出该判断的方法（例如，柳虫血细胞溶解液 [LAL]）。 如果未标记为“无热源”，请选择“N/A”。	☐	☐	☐	
Comments: 评论：						
25. 25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: Select " N/A " if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below. 如果设备和/或配件（如适用）是可重复使用的或最终用户消毒或灭菌的： 如果设备或配件的任何部分都不是可重复使用的或最终用户消毒或灭菌的，请选择“N/A”，否则请完成下面的 a-d。			☐		
	a. a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization. 每个设备和/或配件的标签中提供了清洁方法（如适用）。 如果不可重复使用且在消毒或灭菌之前不需要清洁，请选择“N/A”。	☐	☐	☐	
	b. b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. Select " N/A " if not disinfected (i.e., undergoes terminal sterilization) prior to use. 每个设备和/或配件的标签中提供了消毒方法（如适用）。 如果在使用前未进行消毒（即，经过终末灭菌），请选择“N/A”。	☐	☐	☐	
	c. c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. Select " N/A " if not sterilized (i.e., undergoes disinfection) prior to use. 每个设备和/或配件的标签中提供了灭菌方法（如适用）。 如果在使用前未进行灭菌（即进行消毒），请选择“N/A”。	☐	☐	☐	

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果该项内容存在，请勾选 “是”；如果不需要该项内容，请勾选 “不适用（N/A）” ； 如果该项内容缺失但为必需内容，请勾选 “否”。 随提交材料一并附上本清单的提交者应标明所要求信息所在的页码。如果需要额外空间来标明佐证信息的位置，请在某一要素对应的注释栏中说明。					Yes 是	No 否	N/A 不适用	*Page# 页码
		d.	Device types in this submission are listed in the Federal Register (FR)Notice entitled"Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice,available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable) Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection.Select "N/A"if the device type in the submission is not included in the Reprocessing FR Notice 本次提交的器械类型列于《联邦纪事》（FR）公告中，该公告标题为《某些可重复使用医疗器械上市前通知中的经过验证的使用说明和验证数据要求》（再处理《联邦纪事》公告，可从 https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable获取）。再处理《联邦纪事》公告中确定的器械类型指的是那些更有可能发生微生物传播且存在高感染风险的器械。如果本次提交的器械类型未包含在再处理《联邦纪事》公告中，请选择 “不适用（N/A）”。		☐		☐	
			i.	If device types in this submission are included in the Reprocessing FR Notice,the submission includes protocols and test reports for validating the reprocessing instructions. Select"N/A"if the device type in the submission is not included in the Reprocessing FR Notice. 如果本次提交的器械类型包含在《联邦纪事》再处理公告中，提交材料需包括用于验证再处理说明的方案和测试报告。 如果本次提交的器械类型未包含在《联邦纪事》再处理公告中，请选择 “不适用（N/A）”。	☐	☐	☐	
			Comments:评论：					
	26.	The device has a device-specific guidance document,special controls,and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device If "N/A"is selected,parts a and b below are omitted from the checklist. 该器械有针对其特定的指导文件、特殊控制措施，和（或）在特定器械分类法规中有关于无菌和（或）再处理的要求，且这些适用于该器械。 如果选择 “不适用（N/A）”，则以下 a 和 b 部分将从检查表中省略。				☐		☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
		a. a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的无菌和/或再处理建议。 或者 提交提供了旨在满足适用的法定和/或监管标准的替代方法。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“No”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。	☐	☐	☐	
		b. b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的无菌和/或再处理信息。 或者 提交使用替代缓解措施，并提供理由说明为何替代措施提供了等效的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“否”。请注意，如何处理这些缓解措施的充分性应在实质性审查中进行评估。	☐	☐	☐	
			Comments: 评论：				
F. F.	She 她	Lif 生命					
	27.		posed shelf life/ expiration date stated ement that shelf-life is not applicable because of low lihood of time-dependent product degradation.				

	27.		提出的保质期/过期日期声明 声明由于产品降解的时间依赖性低，因此保质期不适用。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。*提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
		Comments: 评论：				
	28. 28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. Select " N/A " if the device is not provided sterile. 对于无菌设备，提交包括用于建立设备包装将在整个提议的保质期内保持无菌屏障的方法摘要。 如果设备未提供无菌，请选择“N/A”。	☐	☐	☐	
		Comments: 评论：				
	29. 29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH , osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period. 提交包括用于确认设备性能在整个提议的保质期内保持的总结方法（例如，机械性能、涂层完整性、pH 值、渗透压等）。 或者 说明为什么不需要性能数据来确认设备性能特征在保质期内的维护。	☐	☐	☐	
		Comments: 评论：				
G. G.		Biocompatibility If an in vitro diagnostic (IVD) device, select " N/A." The criteria in this section will be omitted from the checklist if " N/A " is selected. 生物相容性 如果是体外诊断（IVD）设备，请选择“N/A”。如果选择“N/A”，本节中的标准将从清单中省略。			☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Submission states that there: (one of the below must be checked) Are direct or indirect tissue-contacting components Are no direct or indirect tissue-contacting components Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) Tissue contact information not needed for this device (e.g., softwareonly device) Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "are no" or "not provided and not needed" is selected, the biocompatibilityrelated criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissuecontacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue. 提交声明如下：（以下选项中必须勾选一个） 有直接或间接接触组织的组件 没有直接或间接接触组织的组件 设备的组织接触状态信息未提供（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要组织接触信息（例如，仅软件设备） 需要组织接触信息或需要不明确 此信息将决定是否以及需要何种类型的额外信息以进行实质等效性判断。 如果选择“没有”或“未提供且不需要”，则下面与生物相容性相关的标准将从清单中省略。如果未提供组织接触状态的信息，并且需要接触信息或其接触状态不明确，请选择“否”。 直接接触组织的设备的一个例子是使用过程中与组织直接接触的植入物。间接接触组织的设备的一个例子是液体在通过未与组织直接接触的设备/设备组件后进入体内。	☐			
Comments: 评论：				
30. 30.	Submission i device compo associated ma including ide 提交 i 设备组成相关 ma，包括 ide	☐	☐		
Comments: 评论：				
31. 31.	Submission i contacting, le device compo 提交我联系，设备组成	☐	☐		
Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页面#
	32. 32.	For a biocompatibility assessment of tissue-contacting components, submission includes: - Each relevant endpoint for the device (as identified in devicespecific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, '" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate). 对于接触组织的组件的生物相容性评估，提交包括： - 设备的每个相关终点（如设备特定指导或 FDA 指导文件“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 A 中所识别的），已得到解决。 - 对于进行的任何测试，测试方案（包括测试物品的识别和描述，包括测试物品是否为最终成品设备，使用“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 F 中推荐的方法，以及通过/不通过标准），以及结果分析（包括适当时的数据点和统计分析的表格），如指导文件“使用国际标准 ISO 10993-1，‘医疗器械的生物评估 - 第 1 部分：在风险管理过程中进行评估和测试”的附件 E 中所述，为每个完成的测试提供。 或者 一份声明，说明不需要进行生物相容性测试，并提供考虑所有相关终点的理由（例如，材料和制造/加工与对照品相同）。	☐	☐		
		Comments: 评论：				
H. H.	Soft 软					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	No 不	N/A 不适用	*Page # *页面#
Submission states that the device: (one of the below must be checked) Does contain software/firmware Does not contain software/firmware Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) Software/firmware information not needed for this device (e.g., surgical suture, condom) Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No." 提交声明该设备：（以下选项中必须勾选一个） 包含软件/固件 不包含软件/固件 未提供设备是否包含软件/固件的信息 （如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要软件/固件信息（例如，外科缝合线，避孕套） 该设备需要软件/固件信息或需求不明确 此信息将决定是否以及需要何种类型的额外信息以进行实质等效性判断。 如果选择“未包含”或“未提供且不需要”，则下面与软件相关的标准将从清单中省略。如果未提供软件信息，并且该信息是必要的或需求不明确，请选择“否”。	☐		

Comments:

评论：

	33.	Submission includes a statement of software level of concern and rationale for the software level of concern 提交材料包含一份关于软件关注等级的声明以及确定该软件关注等级的理由。	☐	☐		
		Comments: 评论：				
	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device. 根据提交者所确定的关注等级，提供了所有适用的软件文档，具体要求如《医疗器械中所含软件的上市前申报资料内容指南》（可从 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices获取该指南）中所述；或者提交材料包含相关信息，用以证明提交者已通过其他替代方法满足了适用的法定或监管标准（即提交者已确定了一种替代方法，并说明了理由）。 注：这一要求同样适用于器械中使用的非内部开发或现成（OTS）软件。	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。			No 不	N/A 不适用	*Page # *页面#
	Comments: 评论：				
I. 我。	Cybersecurity 网络安全				
	Submission states that the device: (one of the below must be checked) Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) Does not contain external interfaces as described above Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) Cybersecurity information not needed for this device (e.g., surgical suture, condom) Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No." 提交声明该设备：（以下选项中必须勾选一个）包含任何外部有线和/或无线通信接口（有线：USB、以太网、SD、CD、RGA 等；无线：Wi-Fi、蓝牙、RF、感应、云等）不包含上述描述的外部接口未提供设备是否具有外部接口的信息（如果勾选此框，请同时勾选以下两个框中的一个）该设备不需要网络安全信息（例如，外科缝合线、避孕套）需要网络安全信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“未包含”或“未提供且不需要”，则下面的网络安全标准将从检查清单中省略。如果未提供网络安全信息，并且该信息是必要的或需求不明确，请选择“否”。		☐		
	35. 35.	All applicable docume described in "Guidanc Submissions for Mana Devices," available at information/search-fda submissions-managem OR Submission includes i has otherwise met the through an alternative an alternate approach 所有适用的文件均在“管理设备提交指南”中描述，您可以在信息/搜索-FDA 提交-管理中找到。 或者 提交包括信息，或者通过替代方法满足要求	☐		
		Comments: 评论：			
J. J.		rical Safety and EMC 电气安全和电磁兼容性			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在元素的评论部分使用。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
Electrical Safety: Submission states that the device: (one of the below must be checked) Does require electrical safety evaluation Does not require electrical safety evaluation Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) Electrical safety information not needed for this device (e.g., surgical suture, condom) Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No." 电气安全： 提交声明该设备：（以下选项中必须勾选一个）需要电气安全评估 不需要电气安全评估 是否需要电气安全评估的信息未提供（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要电气安全信息（例如，外科缝合线，避孕套） 需要电气安全信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。 如果选择“无需”或“未提供且不需要”，则下面的电气安全标准将从清单中省略。如果未提供电气安全信息，并且需要该信息或对该信息的需求不明确，请选择“否”。		☐		
36. 36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale). 提交包括电气安全评估（例如，按照 IEC 60601-1 或等效的 FDA 认可标准，如果适用，还包括特定设备标准）。 或者 提交包括使用未获得 FDA 认可的方法或标准进行的电气安全评估，并且提交包括信息以证明提交者通过这种替代方法满足了适用的法定或监管标准（即，提交者已识别出替代方法或标准并提供了理由）。	☐	☐		
	Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”，如果不需要，请勾选“N/A”，如果需要但未包含，请勾选“否”。 *提交者在提交中包含清单时，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分使用该元素。	Yes 是的	No 不	N/A 不适用	*Page # *页面#
EMC: Submission states that the device: (one of the below must be checked) Does require EMC evaluation Does not require EMC evaluation Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) EMC information not needed for this device (e.g., surgical suture, condom) EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No." EMC： 提交声明该设备：（以下选项中必须勾选一个） 需要进行 EMC 评估 不需要进行 EMC 评估 未提供设备是否需要 EMC 评估的信息（如果勾选此框，请同时勾选以下两个框中的一个） 该设备不需要 EMC 信息（例如，外科缝合线，避孕套） 需要 EMC 信息或需求不明确 此信息将决定是否以及需要什么类型的额外信息以进行实质等效性判断。如果选择“无需”或“未提供且不需要”，则下面的 EMC 标准将从清单中省略。如果未提供 EMC 信息，并且需要该信息或对该信息的需求不明确，请选择“否”。		☐		
Comments: 评论：				
37. 37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDArecognized standard and if applicable, a device-specific standard). OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale). 提交包括电磁兼容性评估（例如，按照 IEC 60601-1-2 或等效的 FDA 认可标准，如果适用，还包括特定设备标准）。 或者 提交包括使用非 FDA 认可的方法或标准进行的电磁兼容性评估，并且提交包括信息以证明提交者通过这种替代方法满足了适用的法定或监管标准（即，提交者已识别出替代方法或标准并提供了理由）。	☐	☐		
Comments: 评论：				

Check"Yes"if item is present,"N/A"if it is not needed and "No"if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located.Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选 “是”；如果项目不需要，请勾选 “不适用（N/A）”；如果项目缺失但为必需的，请勾选 “否”。 * 随提交材料附上本清单的提交者，应注明所要求信息所在的页码。若需更多空间注明支持性信息的位置，请在相应项目的备注栏中填写。				Yes 是	No 否	N/A 不适用	*Page# 页码
K.	Performance Data General If an in vitro diagnostic(IVD)device,select "N/A."The criteria in this section will be omitted from the checklist if "NA"is selected. Performance data criteria relating to IVD devices is addressed in Section L. 性能数据概述 如果是体外诊断（IVD）器械，请选择 “不适用（N/A）”。如果选择了 “不适用（N/A）”，本部分的标准将从清单中省略。 与体外诊断器械相关的性能数据标准在 L 部分中阐述。						☐	
	Comments: 评论：							
	38.	Summaries of the non-clinical laboratory studies and full test reports*are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions,"available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized,submission of a full test report may not be necessary.Refer to 9a.See FDA's guidance"Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,"available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. Select "N/A"if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity. 提供了非临床实验室研究的摘要以及完整的测试报告 *。 * 非临床台架性能测试信息的摘要和完整测试报告的内容建议，可在 FDA 的指南《上市前申报中 非临床台架性能测试信息的推荐内容和格式》中找到，该指南网址为：https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket 。 如果提交者选择声明其符合 FDA 认可的自愿性共识标准，那么可能无需提交完整的测试报告。请参考第 9a 条。可查看 FDA 的指南《医疗器械上市前申报中自愿性共识标准的适当使用》，网址为：https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices 。 如果提交材料合理地未包含性能数据，或者不存在未附合格声明的已完成测试，则选择 “不适用（N/A）”。			☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence(e.g.,comparison to predicate device testing, dimensional analysis,etc.). Select "N/A"if the submission does not include performance data. 提交材料包含对每项测试所产生的数据如何支持实质等效性判定的解释（例如，与对比器械测试结果的比较、尺寸分析等）。 如果提交材料中不包含性能数据，请选择 “不适用（N/A）”。		☐	☐		
	Comments: 评论：							

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but

*Submitters including the checklist with their submission should identify

提交者在提交时应附上清单并进行识别

the page numbers where requested information is located. Use the

所请求信息所在的页码。使用

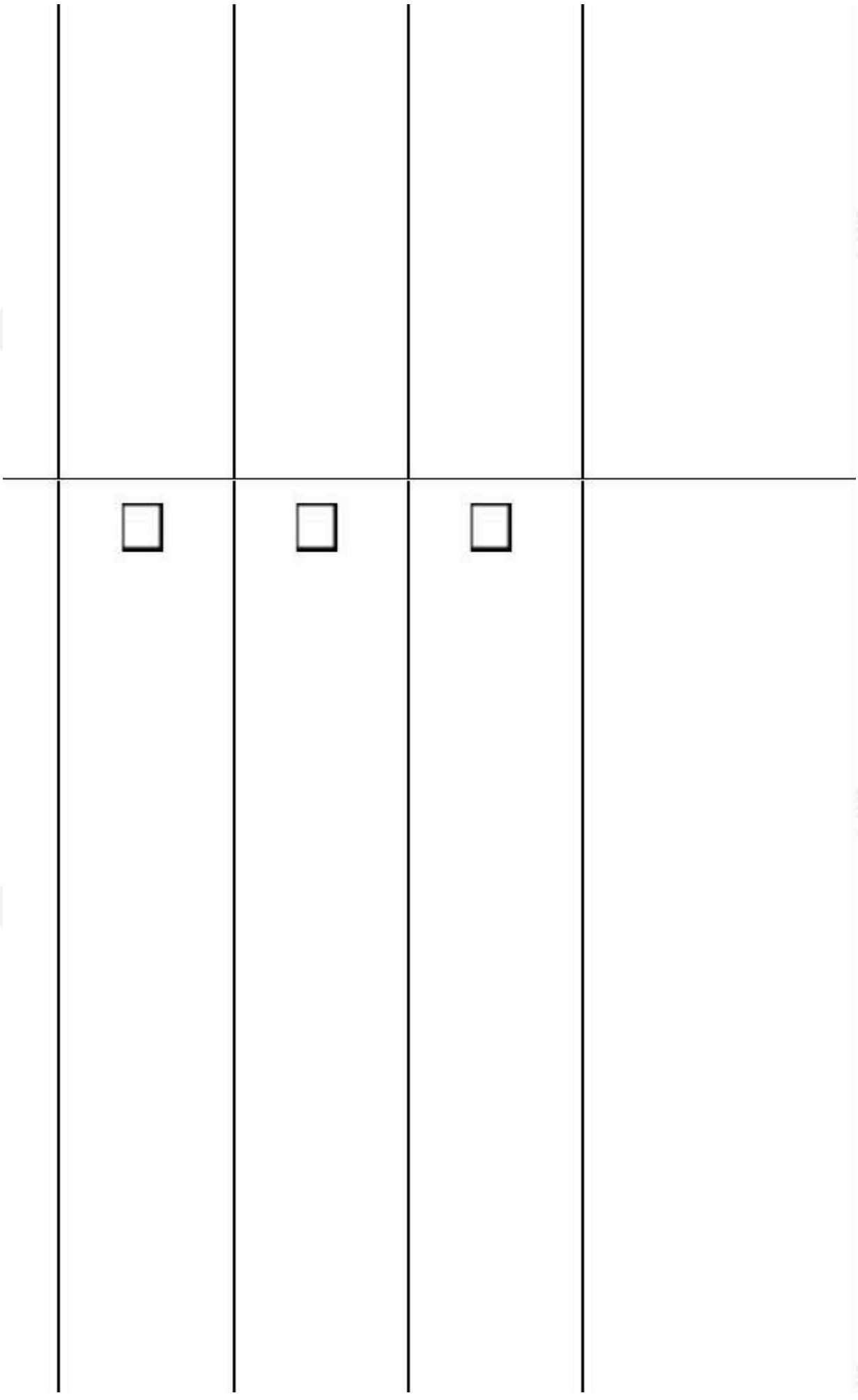
comments section for an element if additional space is needed to identify

如果需要额外空间来识别某个元素，请在评论部分填写

the location of supporting information.

支持信息的位置。

Yes 是	No 否	N/A 不适用
☐		☐
☐	☐	☐



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。			Yes 是的	No 不	N/A 不适用	*Page # *页码#
40. 40.		erature is referenced in the submission, submission des: " " N/A " if the submission does not reference literature. If " is selected, parts a and b below are omitted from the klist. that the applicability of the referenced article to support a tantial equivalence finding should be assessed during the antive review; only the presence of a discussion is required pport acceptance. 在提交中引用了文献，提交描述：“如果提交未引用文献，则为“N/A”。如果选择“”，则省略下面的部分a和b。 在主动审查过程中，应评估引用文章对支持实质等效性发现的适用性；仅需存在讨论即可支持接受。			☐	
	a. a.	Legible reprints or a summary of each article. 每篇文章的清晰复印件或摘要。	☐	☐		
	b. b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate. 讨论每篇文章如何适用于支持目标设备与对照设备的实质等效性。	☐	☐		
		Comments: 评论：				
41. 41.		ach completed animal study, the submission provides the wing: " " N/A " if no animal study was conducted. If " N/A " is ted, parts a-c below are omitted from the checklist. Note his section does not address biocompatibility evaluations, h are assessed in Section G of the checklist. 每个完成的动物研究，提交提供以下内容：“” N/A “如果没有进行动物研究。如果“ N/A ”被引用，则下面的部分 a-c 将从清单中省略。请注意，本节不涉及生物相容性评估，这在清单的第 G 节中进行评估。			☐	
	a. a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120 提交包括一份研究方案，其中包含 21 CFR 58.120 中列出的所有要素。	☐	☐		
	b. b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185 提交包括最终研究报告，其中包含 21 CFR 58.185 中列出的所有要素。	☐	☐		
	c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				

	c.	提交包含一份声明，表明研究是按照适用的 GLP 法规（21 CFR 第 58 部分）进行的，或者如果研究未按照 GLP 法规进行，提交解释了为何不合规不会影响提供的研究数据的有效性，以支持实质等同性的判断。	☐	☐		
		Comments: 评论：				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。				Yes 是的	No 不	N/A 不适用	*Page # *页面 #
L. L.	Performance Characteristics - In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12)) 性能特征 - 仅适用于体外诊断设备（另见 21 CFR 809.10(b)(12)）						
	Submission indicates that device: (one of the below must be checked) Is an in vitro diagnostic device Is not an in vitro diagnostic device If "is not" is selected, the performance data-related criteria below are omitted from the checklist. 提交表示设备：（以下之一必须被勾选）是体外诊断设备 不是体外诊断设备 如果选择“不是”，则下面与性能数据相关的标准将从清单中省略。						
	42. 42.		ission includes the following studies, as appropriate for the type, including associated protocol descriptions, study s and line data: 使命包括以下研究，具体取决于类型，包括相关的协议描述、研究和线数据：				
		a. a.	Precision/reproducibility 精确度/可重复性	☐	☐	☐	
		b. b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff). 准确性（包括适当的线性；校准物或检测的可追溯性；校准物和/或检测稳定性协议及接受标准；检测截止值；方法比较或与临床结果的比较；基质比较；以及临床参考范围或截止值）。	☐	☐	☐	
		c. c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type). 灵敏度（检测限，LoB，LoD，LoQ，适用于设备类型时）。	☐	☐	☐	
		d. d.	Analytical specificity 分析特异性	☐	☐	☐	
			Comments: 评论：				
	43.		device has a device-specific guidance document, special rols, and/or requirement in a device-specific classification ation regarding performance data that is applicable to the ect device.				

	4 3.		V/A" is selected, parts a and b below are omitted from the klist. 设备具有特定于设备的指导文件、特殊角色和/或在特定于设备的分类中关于适用于该设备的性能数据的要求。 如果选择了“V/A”，则下面的部分 a 和 b 将从清单中省略。	☐	☐	☐	

		Yes 是的	No 不	N/A 不适用	*Page # *页面#
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. 如果项目存在，请勾选“是”；如果不需要，请勾选“N/A”；如果需要但未包含，请勾选“否”。 *提交者在提交时附上清单，应标明所请求信息所在的页码。如果需要额外空间来标识支持信息的位置，请在评论部分填写该元素。					
a. a.	The submission addresses performance data recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review. 提交内容涉及设备特定指导中概述的性能数据建议。 或者 提交提供了一种替代方法，旨在满足适用的法定和/或监管标准。 如果没有适用的设备特定指导，请选择“N/A”。如果提交未包括任何遗漏信息的理由或上述任何替代方法，请选择“No”。请注意，设备特定指导等中建议的充分性应在实质性审查期间进行评估。	☐	☐	☐	
b. b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Select " N/A " if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review. 提交包括针对适用于该设备的特殊控制或设备特定分类法规中规定的相关缓解措施的性能数据。 或者 提交使用替代缓解措施，并提供理由说明这些替代措施为何提供等效的安全性和有效性保证。 如果没有适用的特殊控制或设备特定分类法规，请选择“N/A”。如果提交未包括任何遗漏信息或上述任何替代方法的理由，请选择“否”。请注意，如何处理这些缓解措施的充分性应在实质性审查期间进行评估。	☐	☐	☐	
	Comments: 评论：				