

Insight beyond Regulations ™

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U.S. Medical Device Market

美国医疗器械市场

The 2025 Medical Device Market in the United States is ~190.7 Billion USD 2025 年美国医疗器械市场规模约为 1907 亿美元

~190.7 Billion USD = 1365.31 Billion Yuan

~1907 亿美元 = 1.365 万亿元人民币

The Compound Annual Growth Rate anticipated for 2025 – 2029 is 5.19% 预计 2025 年至 2029 年的复合年增长率为 5.19%



Top 5 Things You Need To Know To Enter The U.S. FDA Regulated Medical Device Market

进入美国 FDA 监管的医疗器械市场您需要了解的 5 件事



FDA Pathways and Oversight FDA 途径和监督

Applications to enter the Road to Commercialization 进入商业化之路的申请

Premarket Pathways:上市前途径:

- Premarket Approval (PMA)
 上市前批准 (PMA)
- De Novo 从头
- Humanitarian Device Exemption 人道主义设备豁免
- 510(k) Substantial Equivalence
 510(k) 实质等同

Postmarket Oversight:上市后监督:

- Quality System Regulation
 品质体系规定
- Adverse Event Reporting (MDR)不良事件报告 (MDR)
- Recalls and Corrections
 召回和更正
- FDA Inspections and Audits
 FDA 检查和审计

Means to stay in the Commercialized Market 留在商业化市场的手段







Road to Commercialization 商业化之路

21 CFR Part 820 and ISO 13485

21 CFR 第 820 部分和 ISO 13485

01

02

Regulatory Strategy

监管策略

Submission Pathway

提交途径



Submission and Approval

提交及批准



Documentation and Data

文件和数据







How Does FDA Regulate Medical Devices? FDA 如何监管医疗器械?

21 CFR Part 820, is a set of regulations enforced by the U.S. Food and Drug Administration (FDA) that outlines the current good manufacturing practices (CGMP) for medical devices. It covers various aspects of the manufacturing process, including design, production, labeling, packaging, storage, and servicing of medical devices to ensure they are safe and effective for their intended use.

美国联邦法规》第 21 卷第 820 部分是美国食品药品监督管理局 (FDA) 实施的一套法规,概述了现行的医疗器械药品生产质量管理规范 (CGMP)。它涵盖了制造过程的各个方面,包括医疗器械的设计、生产、标签、包装、储存和服务,以确保它们对其预期用途安全有效。



How Does FDA Regulate Medical Devices?* FDA 如何监管医疗器械?

21 CFR Part 820 has been amended to align more closely with ISO 13485:2016. The FDA issued a final rule on January 31, 2024, to incorporate the quality management system requirements of ISO 13485 into 21 CFR Part 820. This alignment aims to harmonize the FDA's Quality System Regulation (QSR) with international standards, promoting consistency and reducing regulatory burdens for medical device manufacturers. FDA will begin enforcement of QMSR requirements on February 2, 2026.

21 CFR 第 820 部分已修订,以与 ISO 13485:2016 更加一致。FDA 于 2024 年 1 月 31 日发布了最终规则,将 ISO 13485 的质量管理体系要求纳入 21 CFR 第 820 部分。这一调整旨在使 FDA 的质量体系法规 (QSR) 与国际标准相协调,促进一致性并减轻医疗器械制造商的监管负担。FDA 将于 2026 年 2 月 2 日开始执行 QMSR 要求。



How Does FDA Regulate Medical Devices? FDA 如何监管医疗器械?

The revised regulation is now referred to as the Quality Management System Regulation (QMSR) or Quality System (QS) Regulation, and it includes additional concepts to ensure there are no inconsistencies with other applicable FDA requirements.

修订后的法规现称为质量管理体系法规 (QMSR) 或质量体系 (QS) 法规,它包含额外的概念,以确保与其他适用的 FDA 要求不存在不一致。

ISO Certification is not required to meet the new QMSR requirements located in 21 CFR Part 820.

无需 ISO 认证即可满足 21 CFR 第 820 部分中的新 QMSR 要求



How Does FDA Regulate Medical Devices? FDA 如何监管医疗器械?

FDA is developing new inspection processes to align with the QMSR requirements.

FDA 正在制定新的检查流程以符合 QMSR 要求。

If a company does not meet QMSR regulations during an FDA inspection, an FDA Form 483 will be issued. If the FDA Form 483 is not addressed to FDA's satisfaction or if the circumstances are high risk, the FDA will issue a Warning Letter.

如果公司在 FDA 检查期间不符合 QMSR 规定,FDA 将发出 FDA 表格 483。如果 FDA 表格 483 的填写方式不符合 FDA 的要求或情况风险较高,FDA 将发出警告信。



If a medical device manufacturer fails to adequately correct violations cited in a 483 or Warning Letter, especially related to:

如果医疗器械制造商未能充分纠正 483 或警告信中提到的违规行为,尤其是涉及以下方面的违规行为:

- Quality System Regulation (QSR) noncompliance (21 CFR Part 820)
 质量体系法规 (QSR) 不合规 (21 CFR 第 820 部分)
- Lack of proper premarket notification or approval (e.g., no 510(k), PMA)
 缺乏适当的上市前通知或批准(例如,没有510(k)、PMA)
- Misbranding or adulteration 贴错标签或掺假
- Refusal of FDA inspection 拒绝FDA检查
- ...then the FDA may escalate the issue to an **import alert** under **Section 801(a) of** the FD&C Act, particularly for "appearance" of violation.
- ...那么 FDA 可能会根据《联邦食品、药品和化妆品法案》第 801(a) 条将问题升级为进口警报,特别是对于"出现"违规行为的情况。







Regulatory Submission Strategy

监管提交策略

A well-structured FDA regulatory submission strategy for a medical device will ensure efficient market entry while maintaining compliance with regulations. 结构良好的医疗器械 FDA 监管提交策略将确保高效的市场准入,同时保持对法规的合规性

Device Classification 设备分类

Pre-submission engagement with FDA 与 FDA 的提交前合作

Evidence development 提交前参与

Submission preparation 提交准备

QMSR compliance QMSR 合规性

Labeling and Unique Device Identification (UDI) 标签和唯一设备标识 (UDI)

Post-Market Planning 上市后规划



How Does FDA Classify Medical Devices? FDA 如何对医疗器械进行分类?

Medical devices are classified into three main categories by the FDA based on the level of risk they pose to patients and users:

FDA 根据医疗器械对患者和用户构成的风险程度,将其分为三类:

 Class I: These devices present the lowest risk and are subject to the least regulatory control. Examples include bandages, latex gloves, tongue depressors, and handheld surgical instruments. Most Class I devices are exempt from premarket notification requirements.

I 类:这些设备风险最低,受到的监管控制也最少。例如绷带、乳胶手套、压舌板和手持式手术器械。大多数 I 类设备无需遵守上市前通知要求。



How Does FDA Classify Medical Devices? FDA 如何对医疗器械进行分类?

 Class II: These devices pose a moderate risk and require greater regulatory controls to ensure safety and effectiveness. Examples include powered wheelchairs, blood pressure cuffs, contact lenses and infusion pumps. Class II devices typically require premarket notification (510(k)).

Ⅱ 类: 这些设备具有中等风险,需要加强监管控制以确保安全性和有效性。例如电动轮椅、血压袖带、隐形眼镜和输液泵。 Ⅱ 类设备通常需要上市前通知 (510(k))。



How Does FDA Classify Medical Devices? FDA 如何对医疗器械进行分类?

• Class III: These devices present the highest risk and are subject to the most stringent regulatory controls. Examples include implantable pacemakers and heart valves. Class III devices usually require a premarket application (PMA) to ensure their safety and effectiveness.

Ⅲ类:此类设备的风险最高,且受到最严格的监管控制。例如植入式起搏器和心脏瓣膜。Ⅲ类设备通常需要上市前批准 (PMA) 以确保其安全性和有效。



Step 3 21 CFR Part 820 步骤3 Regulatory and ISO 13485 Strategy 21 CFR 第 820 监管策略 部分和 ISO 13485 02 04 01 03 05





The FDA offers several pathways to bring your device to market.

Selecting the correct one saves time and resources.

FDA 提供了多种将您的设备推向市场的途径。选择正确的可以节省时间和资源

Premarket Approval (PMA): 上市前批准 (PMA)

Most Class III devices - These are the complex devices that require a PMA, a rigorous FDA process with clinical data. Class III devices are usually life-sustaining or life-supporting.

Ⅲ 类器械 - 这些是复杂的器械,需要 PMA,这是一个严格的 FDA 流程,包含临床数据。Ⅲ 类器械通常是维持生命或生命支持的。

Class III Less Common, but Notable Examples from China: Ⅲ 类 不太常见,但值得注意的例子来自中国:

•Implantable pacemakers – While rare, some components or lower-tier assemblies might be sourced from Chinese manufacturers.

植入式心脏起搏器——虽然很少见,但一些部件或低端组件可能来自中国制造商。

•Artificial heart valves – Again, these are not mass exported, but some parts and materials may originate in China.

人工心脏瓣膜——同样,这些不是大规模出口的,但一些零件和材料可能产自中 国。

•Cochlear implants – Advanced hearing devices with imported components.

人工耳蜗——采用进口部件的先进助听器。



De Novo Pathway: 从头途径:

- For devices that are novel, have no comparable approved device, and pose a low-to-moderate risk.
 - 适用于具有创新性、没有可比对的已批准设备,且风险为低到中等的医疗器械。
- Provides a streamlined approach for innovative technologies. 为创新技术提供简化的方法。



Humanitarian Device Exemption (HDE):

人道主义设备豁免 (HDE):

 For devices intended to treat or diagnose conditions affecting fewer than 8,000 patients annually.

用于治疗或诊断每年影响不到 8,000 名患者的疾病的设备。

 Requires less evidence than PMA but still ensures safety and probable benefit.

需要的证据比 PMA 少,但仍可确保安全性和可能的益处。



Premarket Notification - 510(k):

上市前通知 (510(k)):

Class II devices often require a 510(k) premarket notification.

- Ⅱ 类器械通常需要 510 (k) 上市前通知。
 - Applicable to Class I and II devices unless exempt.
 - 适用于 | 类和 || 类设备,除非获得豁免。
 - Manufacturers must prove the device is substantially equivalent to an already marketed device (the Predicate).
 制造商必须证明该设备在实质上等同于已上市的设备(即 Predicate)
 - This pathway is faster and less complex than the De Novo and PMA processes.
 - 该途径比 PMA 过程更快、更简单。



Class II - Moderate Risk II 类 - 中等风险

Commonly Exported Examples from China:中国出口的常见示例:

- Powered wheelchairs With batteries and controls, these fall under Class II.
 电动轮椅 配有电池和控制器,属于Ⅱ类。
- Infusion pumps Used to deliver medication, fluids, or nutrients to patients.
 输液泵 用于向患者输送药物、液体或营养物质。
- X-ray machines Most imaging diagnostic equipment.
 X 光机 大多数成像诊断设备。
- Pulse oximeters Especially in demand post-COVID, these measure oxygen levels non-invasively.
 - 脉搏血氧仪 尤其是在 COVID 之后的需求,它们可以非侵入性地测量氧气水平。
- Surgical drapes and gowns More protective, especially in OR settings.
 手术单和手术服 更具保护性, 尤其是在手术室环境中。

What are Exempt Medical Devices?* 什么是豁免医疗器械?

Pre-amendment devices/ Prior to May 28, 1976 预先修正装置/1976 年 5 月 28 日之前

FDA determined that the devices do not require strict regulation FDA 确定这些设备不需要严格监管 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Most must still meet General Controls including requirements for: 大多数仍必须满足一般控制措施,包括以下要求:

- Adulteration 掺假
- Misbranding 错误品牌
- Records and Reports 记录和报告
- Good Manufacturing Practices 良好生产规范
- Registration and Listing 注册及上市
- Premarket Notification 上市前通知



Class I Medical Devices:

第一类医疗器械:

Many low-risk Class I devices are exempt from premarket submissions but still require compliance with labeling and manufacturing controls. However, some Class I device are not exempt and do require a 510(k) application. Examples of these devices are Galactose U.V. Method, many dental handpieces and accessories, as well as antigen and antiserum reagents for Epstein-Barr virus.

许多低风险 I 类器械无需进行上市前提交,但仍需遵守标签和制造控制。但是,一些 I 类器械不免于提交,需要进行 510(k) 申请。这些器械的例子包括半乳糖紫外线法、许多牙科手机和配件,以及 Epstein-Barr 病毒的抗原和抗血清试剂。

Class II exempt Medical Devices:

Ⅱ类豁免医疗器械

Certain low-risk Class II devices may be exempt from premarket submissions but still require compliance with labeling and manufacturing controls. Class II exempt examples include Acid Hematin Assay, Cell indices, and blood storage refrigerators and freezers.

某些低风险 II 类器械可能无需进行上市前提交,但仍需遵守标签和制造控制。II 类豁免器械包括酸性血红素测定、细胞指数以及血液储存冰箱和冰柜。

510(k) Application 510(k) 申请

Most common pathway is 510(k) 最常见的途径是 510(k)

Moderate Risk devices

中等风险设备

 Demonstrate substantial equivalence rather than conduct full clinical trials

证明等效性而不是完整的临床试验

Speed

速度



510(k) Application 510(k) 申请

Key Elements of Substantial Equivalence

实质等同的关键要素

- Same intended use as the predicate
 与 Predicate 具有相同的预期用途。
- Same or Similar Technological Characteristics
 相同或相似的技术特征

If there are different technological characteristics, do they raise new questions of safety and effectiveness?

如果存在不同的技术特征,它们是否会引发新的安全性和有效性问题?

What is a Predicate Medical Device? 什么是 Predicate 医疗器械?

A predicate medical device is a previously approved device that serves as a benchmark for evaluating the safety and effectiveness of new medical devices. When a manufacturer wants to market a new device, they can submit a Premarket Notification (510(k)) to the FDA, demonstrating that their device is substantially equivalent to a legally marketed predicate device.

Predicate 医疗器械是指先前已获批准的设备,用作评估新医疗器械安全性和有效性的基准。

当制造商希望将一款新设备推向市场时,可以向 FDA 提交"上市前通知"(510(k)),证明其设备在实质上等同于一款合法上市的 predicate 医疗器械。

Substantial equivalence means the new device has the same intended use and similar technological characteristics as the predicate device. This process helps streamline the approval of new devices while ensuring they meet safety and efficacy standards.

"实质等同性"意味着新设备具有与 predicate 设备相同的预期用途,并具有相似的技术特征。 该过程有助于简化新设备的审批流程,同时确保其符合安全性和有效性的标准。



Choosing the Predicate 选择 Predicate

- Find an FDA approved device with the same intended use and the same or similar technology characteristics
 - 查找 FDA 批准的具有相同预期用途和相同或相似技术特征的设备
- Determine the approved device's product code which will lead to device classification, regulation number, and testing required
 - 确定批准的设备的产品代码,这将导致设备分类、法规编号和所需的测试

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm



Product Code Classification* 产品代码分类

The FDA product code (3 letter code) significantly impacts the timeline for regulatory clearance/ approval because it determines the classification, review pathway, testing requirements, and whether there is a predicate device.

FDA 产品代码(三个字母的代码)对法规审批的时间安排有重大影响,因为它决定了产品的分类、审评途径、测试要求,以及是否存在 predicate 设备。

- Existing product code → Faster, Predicate device determination, testing identified, generally 510(k) clearance.
 已有产品代码 → 审批更快、确定 Predicate 设备、测试要求明确、通常适用于 510(k) 审批路径。
- No existing product code (novel technology) → generally De Novo or PMA (~9-36 months or more).
 - 没有现有产品代码(新技术)→通常是 De Novo 或 PMA (~9-36 个月或更长时间)。

Device mask, surgical Regulation Description Surgical apparel.

Regulation Medical Specialty General & Plastic Surgery

Review Panel General Hospital

Product Code FXX

Premarket Review Office of Surgical and Infection Control Devices (OHT4)

Infection Control Devices (DHT4C)

Submission Type 510(k)
Regulation Number 878.4040

Device Class 2

Total Product Life Cycle (TPLC) <u>TPLC Product Code Report</u>

GMP Exempt? No

Summary Malfunction
Reporting
Eligible

Implanted Device?

Life-Sustain/Support Device?

Recognized Consensus Standards

•6-406 ASTM F1862/F1862M-17

Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

•6-425 ASTM F2100-19

Standard Specification for Performance of Materials Used in Medical Face Masks

•6-427 ASTM F2101-19

Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

•6-492 ASTM F2100-23

Standard Specification for Performance of Materials Used in Medical Face Masks

•6-493 ASTM F2101-23

Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

•6-504 ASTM F1862/F1862M-24

Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

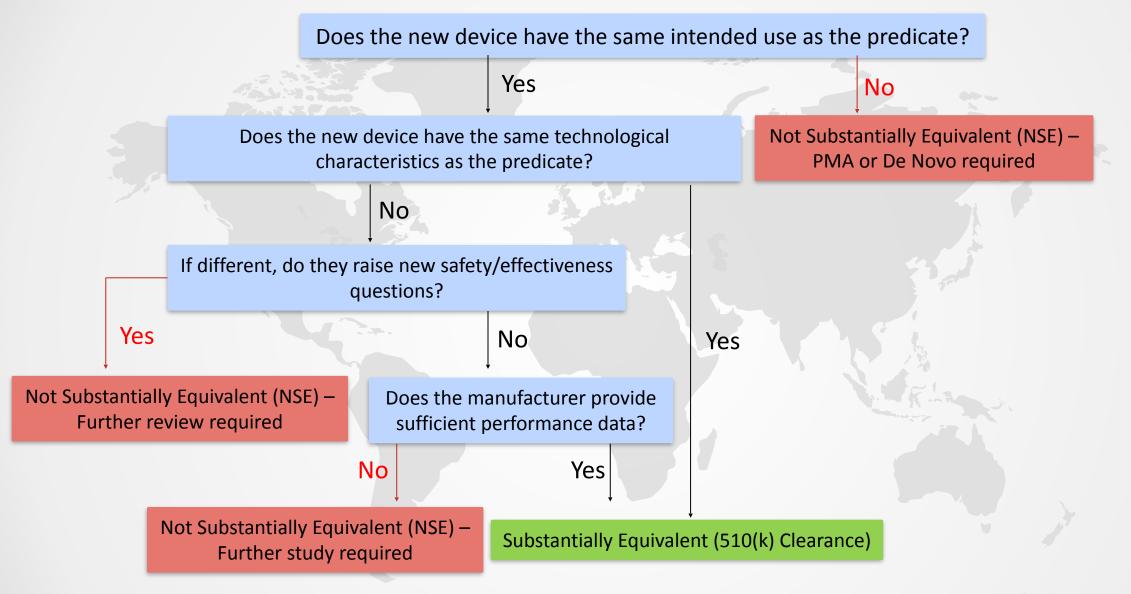
Guidance Document

•Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA



Choosing the Predicate 选择 Predicate

- Note Device Class, Submission Type, Consensus Standards, Guidance Documents, Test requirements
 - 注意设备类别、提交类型、共识标准、指导文件、测试要求
- Go to the total Product Life Cycle (TPLC)
 转至产品总生命周期 (TPLC)
- Premarket Reviews will list manufacturer(s) who have substantially equivalent products for that product code. Also note MDRs and Recalls located here as applicable.
 - 上市前审查将列出具有与该产品代码基本相同的产品的制造商。另请注意此处适用的 MDR 和召回。







是的

不

新设备是否具有与 Predicate 相同的技术特征?

不

如果不同,它们是否会提出新的安全性/有效性

问题?

实质上不等效 (NSE) - 需要

是的

一步审查

不

制造商是否提供足够的性能数据?

不

是的

实质上不等效 (NSE) - 需要进一步研究

PMA 或 De Novo

实质上不等同 (NSE) - 需要

是的

基本等效 (510(k) 许可)



21 CFR Part 820 and ISO 13485

21 CFR 第 820 部分和 ISO 13485

01

02

Regulatory Strategy 监管策略 Submission Pathway 提交途径 Step 4 步骤4

03 04

05

Documentation and Data

文件和数据



FDA Checklist FDA 核查清单

➤ Checklist for Acceptance Review for PMAs PMA 验收审查清单

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas

➤ Checklist for Acceptance Review for De Novo Classification De Novo 分类验收审查清单

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests

➤ Checklist for Acceptance Review for 510(k)s 510(k) 验收审核清单

https://www.fda.gov/medical-devices/premarket-notification-510k/acceptance-checklists-510ks



Documentation and Data 文档和数据

Examples of data that may be included in 510(k) submission: 510(k) 提交中可能包含的数据示例:

- Administrative 行政
- Device Description 设备描述
- Substantial Equivalence 实质等同
- Proposed Labeling 建议标签
- Sterilization消毒
- Shelf Life 保质期

- Biocompatability生物相容性
- Software 软件
- Cybersecurity
 网络安全
- Electrical Safety
 电气安全
- Performance Data 性能数据
- Performance Characteristics
 性能特征



Regulatory Pathway	510(k) Clearance	De Novo	Premarket Approval (PMA)
Typical FDA Review Time (months)	3-5	5-12	12+
Total Time to Market* including preparation (months)	6-12	9-18	18-36+
Device Risk Level (Most)	Class II	Class I or II (novel devices)	Class III
Clinical Trial Required	Rarely	Sometimes	Always
Test Requirements	Bench tests and some biocompatibility	Bench, performance and possible clinical testing	Extensive clinical trials & safety studies
Likelihood of FDA questions/ delays	Moderate	High	Very High

^{*}Assuming all documents are submission ready.

监管途径	510 (k) 许可	从头开始	上市前批准 (PMA)
FDA 审查时间(月)	3-5	5-12	12+
包括准备在内的总上市时间 (月)	6-12	9-18	18-36 岁以上
设备风险等级(最高)	Ⅱ类	Ⅰ 类或 Ⅱ 类 (新型设备)	III 级
需要临床试验	很少	有时	总是
测试要求	台架试验和一些生物 相容性	台架试验、性能测 试和可能的临床测 试	广泛的临床试验和 安全性研究
延迟的可能性	缓和	高的	非常高

假设所有文件均已准备好提交。



Tips for Manufacturers 给制造商的建议

Factors That Can Negatively Affect Approval Time

可能对审批时间产生负面影响的因素

- Quality of submission Incomplete or unclear data leads to FDA requests for additional information, delaying the process.
 - 提交的质量——数据不完整或不清楚会导致 FDA 要求提供更多信息,从而延迟流程。
- Testing requirements Some devices require biocompatibility, electrical safety, or performance testing, which can add months.
 - 测试要求——某些设备需要进行生物相容性、电气安全或性能测试,这可能需要数月时间。

Tips for Manufacturers 给制造商的建议

Factors That Can Negatively Affect Approval Time

可能对审批时间产生负面影响的因素

- FDA workload High submission volume can slow processing times.
 FDA 工作量——提交量大可能会减慢处理时间。
- Refusals to Accept (RTA) If the FDA finds the submission incomplete, it can reject it before formal review, causing delays.
 - 拒绝接受 (RTA) 如果 FDA 发现提交的内容不完整,则可以在正式审查之前拒绝它,从而导致延误。
- Wrong Product Code
 错误的产品代码



Top Mistakes When Filing a 510(k) 申请 510(k) 时最常犯的错误

Factors That Can Negatively Affect Approval Time 可能对审批时间产生负面影响的因素

- Confusing intended use with indicated use 混淆预期用途与指示用途
- Ignoring the device's regulatory history 忽视设备的监管历史
- Not following the 510(k) submission checklist 未遵循 510(k) 提交清单
- Failing to provide adequate Risk Management practices
 未能提供足够的风险管理实践
- Different intended use or technical characteristics 不同的预期用途或技术特性



Top Mistakes When Filing a 510(k) 申请 510(k) 时最常犯的错误

Factors That Can Negatively Affect Approval Time 可能对审批时间产生负面影响的因素

- Not demonstrating equivalence to the predicate or comparing the wrong predicate device
 - 未能证明与 Predicate 的等同性,或选择了错误的 Predicate 设备进行比对。
- Glossing over FDA instructions and guidance
 忽视 FDA 的指示和指导
- Not providing all of the expected testing and results or not providing validation testing

未提供所有预期的测试和结果或未提供验证测试



Strategies to shorten the time required for FDA submission, clearance, and approval: 缩短FDA提交、审批和批准所需时间的策略

- Early Regulatory Planning: Start planning for regulatory requirements early in the development process. This includes understanding the specific requirements for your device and preparing the necessary documentation in advance.
 - 早期监管规划:在开发过程的早期就开始规划监管要求。这包括了解设备的具体要求并提前准备必要的文档。
- Design Research: Conduct thorough design research to ensure that your device meets user needs and regulatory standards from the outset. This can help avoid costly and time-consuming revisions researched.
 - 设计研究:进行彻底的设计研究,确保您的设备从一开始就符合用户需求和监管标准。这可以帮助避免昂贵且耗时的修订研究。



Strategies to shorten the time required for FDA submission, clearance, and approval: 缩短FDA提交、审批和批准所需时间的策略

• Abbreviated 510(k) Program: This program uses guidance documents, special controls, and recognized standards to streamline the review process. If the device conforms to these standards, the review can be expedited.

简化版 510(k) 计划:该计划使用指导文件、特殊控制和公认标准来简化审查流程。如果设备符合这些标准,则可以加快审查速度。

 Pre-Submission Meetings: Engaging in pre-submission meetings with the FDA can help clarify requirements and address potential issues before the formal submission, leading to a smoother and quicker review.

提交前会议:与 FDA 进行提交前会议有助于在正式提交之前澄清要求并解决潜在问题,从而使审查更加顺利、快捷。

Strategies to shorten the time required for FDA submission, clearance, and approval: 缩短FDA提交、审批和批准所需时间的策略

• Electronic Submission: Utilizing electronic submission templates can facilitate faster processing and review by the FDA.

电子提交:利用电子提交模板可以促进 FDA 更快地处理和审查。

 Cross-Functional Collaboration: Enhance collaboration between various departments such as R&D, quality assurance, regulatory, and production. Effective communication and collaboration can minimize regulatory bottlenecks and speed up the approval process.

跨职能协作:加强研发、质保、监管、生产等各部门之间的协作。有效的沟通与协作可以最大限度地减少监管瓶颈,加快审批流程。



Strategies for manufacturers to shorten the time required for FDA submission, clearance, and approval:制造商缩短FDA提交、清关和批准所需时间的策略:

• Al Tools for Design and Compliance: Integrate Al tools to automate routine tasks like documentation, design simulations, and compliance checks. This can shorten product design cycles and facilitate quicker regulatory approvals.

用于设计和合规的 AI 工具:集成 AI 工具来自动执行文档、设计模拟和合规性检查等日常任务。这可以缩短产品设计周期并加快监管审批速度。

An estimate of time reduction was researched, and this data is not available 对时间减少的估计值进行了研究,但没有提供该数据。



21 CFR Part 820 and ISO 13485 21 CFR 第 820 部分和 ISO 13485

01

Regulatory Strategy

监管策略

02

Submission Pathway 提交途径

03

Documentation and Data

文件和数据



Submission and Approval

提交及批准



Step 5

步骤5

Standard FDA Review vs. Third Party Review for 510(k) 标准 FDA 审查与 510(k) 第三方审查

510(k) Review Comparison 510(k) 审查比较

Standard U.S. FDA Review	Third Party Review
标准美国 FDA 审查	第三方审查
Submit to FDA	Submit to Accredited Third Party
提交给FDA	提交给认可的第三方
15-day initial review period 15天初步审查期	30-60-day assessment of equivalence and written recommendation 30-60 天的等效性评估和书面推荐
60-day Substantive Review	30-day decision then send to FDA
60 天实质性审查	30 天决定,然后发送给 FDA
	FDA then has 30 days to issue a final decision FDA 随后有 30 天的时间发布最终决定
Total time: 90+ days*	Third Party Review 60-90 days + FDA 30 days = 90-120+ days*
总时间: 90+天*	第三方审查 60-90 天 + FDA 30 天 = 90-120+ 天*

^{*}Review times for each may be exceeded due when questions that must be responded to before progressing stop the review clock.

当在进展之前必须回答的问题停止审核时钟时,每个审核时间可能会超出。

FDA Standard Review for a 510(k) application FDA 对 510(k) 申请的标准审查

The FDA aims to complete the review of a Traditional 510(k) submission within 90 calendar days from the date of receipt. FDA will perform an acceptance review within 15 days of receipt of a 510(k) application. The FDA checks the 510(k) submission for completeness, if incomplete, the FDA may issue an RTA (Refuse To Accept) notification, and the 90-day review clock will not begin.

FDA 的目标是在收到传统 510(k) 申请之日起 90 个日历日内完成审核。 FDA 将在收到 510(k) 申请后 15 天内进行验收审核。FDA 检查 510(k) 申请的完整性,如果不完整,FDA 可能会发出 RTA(拒绝接受)通知,并且 90 天的审核时间不会开始。



FDA Standard Review for a 510(k) application FDA 对 510(k) 申请的标准审查

After the acceptance review is passed, the FDA will conduct a substantive review. detailed review, assessing substantial equivalence. If more data is needed, the FDA may place the submission on an AI Hold (Additional Information), pausing the 90-day clock. The 90-day clock resumes only after the FDA receives a complete response.

验收审查通过后,FDA将进行实质性审查。详细审查,评估实质等效性。如果需要更多数据,FDA可能会将提交的内容置于 Al Hold (附加信息)状态,暂停 90 天的审批时间。只有在 FDA 收到完整回复后,90 天的审批时间才会恢复。

Interactive Review: If minor issues exist, the FDA may ask for quick clarifications without stopping the clock.

交互式审查:如果存在小问题,FDA可能会要求快速澄清,而不会停止计时。



Electronic Submission 疗器械的上市后要求

- All 510(k) and PMA submissions must be filed electronically using the FDA's Electronic Submission Template and Resource (eSTAR) system, unless exempted.
 - 所有 510(k) 和 PMA 提交均须使用 FDA 的电子提交模板和资源 (eSTAR) 系统以电子方式提交,除非获得豁免。
- Starting October 1, 2025, all De Novo submissions must be filed electronically using the FDA's Electronic Submission Template and Resource (eSTAR) system.
 - 自 2025 年 10 月 1 日起,所有 De Novo 提交都必须使用 FDA 的电子提交模板和资源 (eSTAR) 系统以电子方式提交。



Electronic Submission 疗器械的上市后要求

The 510(k) submission process demands considerable time and resources. If you find preparing these submissions to be a daunting task, consider enlisting the expertise of Compliance Insight to support your project.

510(k) 提交流程需要大量时间和资源。如果您发现准备这些提交文件是一项艰巨的任务,请考虑聘请 Compliance Insight 的专业知识来支持您的项目。

