Case Study 1: Selecting a Predicate Device for a 510(k) Submission

A mid-sized medical device company was preparing to launch a new knee replacement implant in the U.S. market. The primary challenge was selecting the right predicate device to support their 510(k) submission.

They faced a critical decision—choosing an appropriate predicate was essential to establish substantial equivalence and avoid unnecessary FDA scrutiny. With numerous similar devices available, finding one that aligned with the new product's materials, indications for use, and design characteristics proved difficult. A misstep here could trigger additional data requests, reclassification, or costly delays.

Compliance Insight partnered with the company's regulatory team to conduct targeted research using FDA's public databases and competitor analyses. Drawing on our extensive experience, we guided them to a predicate cleared under Product Code JWH. We helped develop engineering rationale and comparative testing focused on the implant's novel locking mechanism.

Thanks to this strategic guidance, the FDA accepted the submission with minimal questions, and the company moved forward efficiently with its clearance process.

Key Takeaway: Selecting the right predicate requires more than product similarity—it demands alignment of intended use and technical characteristics. Partnering with Compliance Insight early can streamline the path to market.

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