

MASTER YOUR 510(K). NAVIGATE U.S. MARKET ACCESS.

End-to-end FDA 510(k) strategy, substantial equivalence assessment, eSTAR submission & review support.

Turn your device evidence into a coherent, defensible 510(k) submission aligned with FDA expectations.

YOUR CHALLENGES



PATHWAY & PREDICATE STRATEGY How to define the right 510(k) approach and identify an appropriate predicate for your device?



SUBSTANTIAL EQUIVALENCE EVIDENCE How to build a convincing substantial equivalence case supported by appropriate performance and technical evidence?



FDA SUBMISSION SCRUTINY How to prepare a complete eSTAR submission and address FDA questions throughout the review?

OUR APPROACH

01 ASSESS

- Device classification and applicable 510(k) pathway
- Evaluation of predicate candidates and substantial equivalence strategy
- Assessment of existing evidence and identification of submission gaps



02 IMPLEMENT

- Prepare the substantial equivalence rationale
- Structure technical, performance and supporting evidence
- Prepare and compile the 510(k) submission in eSTAR



03 ASSURE

- Perform submission completeness and consistency
- Support FDA interactions and Additional Information responses
- Provide technical support throughout the FDA review process

YOUR BENEFITS



CLEAR 510(K) STRATEGY

A well-defined pathway and predicate strategy aligned with your device and U.S. regulatory requirements.



ROBUST SUBSTANTIAL EQUIVALENCE CASE

A coherent, evidence-based rationale connecting device characteristics, performance data and intended use.



FDA-READY SUBMISSION

A complete, consistent eSTAR submission backed by expert support throughout FDA review.

**READY TO BUILD YOUR
510(K) SUBMISSION?**

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