CONSULTING SERVICES

Pre-Submissions

Pre-Submission Meeting Request using the new FDA PreSTAR v.1.1 template (Preparation, Teleconference, & Meeting Minutes).

Determination of the regulatory pathway, predicate selection, or developing a testing plan may require additional hourly consulting if an FDA Special Controls Guidance is not obvious or your device is significantly different from cleared devices.

Estimated Cost of Pre-Submission: $5,000 *No FDA User Fee

510(k) Submission

510(k) Submission or De Novo Request using the new FDA non-IVD eSTAR v5.3 and IVD eSTAR v5.3 templates (includes assisting with AI response requests).

Bundled submissions or submissions with multiple predicates may cost more.

Estimated Cost of 510(k) or De Novo: $17,500 *FDA User Fee is Separate

513(g) Submission

We recommend the following content to be included if you believe your device requires a De Novo:

- Device Description
- Draft Instructions for Use (user manual)
- Draft Labeling
- Classification Rationale as Class 1 or 2
- Proposed Regulation Name & Number
- Proposed Special Controls
- Draft Benefit/Risk Analysis
- Risk Mitigation Table
- Alternative Procedures & Techniques to the Subject Device's Technology
- Your Efforts to Identify a Potential Predicate Device

Estimated Cost of 513(g): $6,000 *FDA User Fee is Separate

Breakthrough Device Designation

Since the submission content is nearly identical for a Breakthrough and a STeP, if a BDD is denied, we are willing to revise your submission to a STeP and resubmit.

The Estimated Cost of Breakthrough Device Designation: $3,000 *No FDA User Fee

All Pricing as of July 16, 2025

CONSULTING SERVICES

Regulatory Pathway, Predicate ID, & Testing Plan

For FDA Submissions: This is typically only needed when there is no FDA Special Controls Guidance or your device is significantly different from cleared devices.

Estimated Cost of Reg. Pathway, Pred. ID, & Testing Plan: $1,500 *No FDA User Fee

Human Factors Documentation

- Define User Group, Use Environment, & User Interface
- Identification of Use Errors (including Task Analysis)
- Critical Task Analysis
- Creation of User-Related Risk Analysis (URRA)
- Creation of Summative Usability Test Protocol

Note: May require additional time for product classification with many use errors reported or for devices with multiple user groups.

Estimated Cost of Human Factors Documentation: Please Contact Us *No FDA User Fee

US Agent Services

Includes Initial FDA Registration. Prices do not include the FDA Establishment Registration Fee. We can provide you with a video showing you how to make the payment to the FDA.

Initial Registration: $800 Annual Renewal: $600

Hourly Consulting Rates

President: Rob - $350/hour

Senior Regulatory Consultants: Shaily & Matthew - $275/hour

Executive Assistants: Tif & Becca - $200/hour

All Pricing as of July 16, 2025