

Description of Consulting Services

Pre-Submissions

Pre-submission Meeting Request using the new FDA [PreSTAR v1.1](#) template (preparation, teleconference, and 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.*

\$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](#) template (includes assisting with responses AI requests) - *Bundled submissions or submissions with multiple predicates will cost more.*

\$17,500

*FDA User Fee is extra

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 (i.e., user manual)
- draft labeling
- classification rationale as Class 1 or 2
- a proposed regulation name and number
- proposed special controls
- draft benefit/risk analysis
- risk mitigation table
- alternative procedures and techniques to the subject device's technology
- your efforts to identify a potential predicate device

\$6,000

*FDA User Fee is extra

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 at no additional charge.

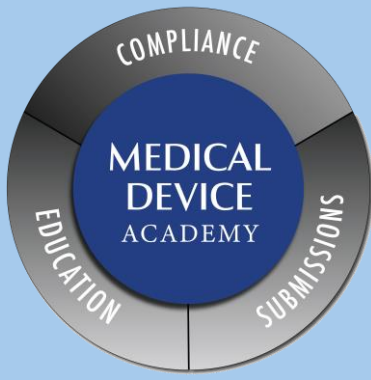
\$3,000

*No FDA User Fee

Regulatory Pathway, Predicate Selection, & Testing Plan

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

\$1,500



Description of Consulting Services

Human Factors Documentation

- Define user group, use environment, and the user interface
- Identification of Use Errors (including task analysis)
- Critical Task Analysis
- Creation of a User-Related Risk Analysis (URRA)
- Creation of Summative Usability Test Protocol

Hourly
Consulting
Only

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

US Agent Services (including initial FDA Registration)

Initial - \$800

*Prices do not include the FDA Establishment Registration Fee

Renewals - \$600

We can provide you with a video showing you how to pay the fee.

Hourly Consulting Rates

President: Rob Packard - \$350/hr

Senior Regulatory Consultants: Bhoomika & Matthew - \$275/hr

Executive Assistants: Tiffany & Becca - \$200/hr

