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.*** ***No FDA User Fee**	**$5,000**
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.*** ***FDA User Fee is extra**	**$17,500**
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** ***FDA User Fee is extra**	**$6,000**
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.** ***No FDA User Fee**	**$3,000**
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**

Pricing as of October 18, 2024

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

Renewals - $600

***Prices do not include the FDA Establishment Registration Fee**

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: Tifany & Becca - $200/hr

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