Consulting Services Pricing

Effective August 1, 2026

Hourly Consulting Rates

President: Rob Packard	**$450**
Senior Regulatory Consultants: Matthew, Tom, & Bill	**$375**
Regulatory Consultants: Greg, Rachelle, & Polly	**$300**
Assistants: Tif, Becca, Sabrina, & Danielle	**$225**

All projects are billed on an hourly basis.

Pre-Submission Meeting Request

Using the latest FDA PreSTAR template.
Includes preparation, teleconference, and meeting minutes.
Determination of regulatory pathway, predicate selection, or development of testing plan may require additional hourly consulting if FDA Special Controls Guidance is not obvious, or if device is significantly different from cleared devices.
Does not include Protocols or FDA User Fee.

Est. Cost of Project: $6,000

510(k) Submission

Using the latest FDA non-IVD or IVD eSTAR templates.
Includes assistance with AI Response Requests.
Bundled Submissions or submissions with multiple predicates may cost more.
Does not include FDA User Fee.

Est. Cost of Project: $20,000

De Novo Submission

Using the latest FDA non-IVD or IVD eSTAR templates.
Includes assistance with AI Response Requests.
Bundled Submissions or submissions with multiple predicates may cost more.
Does not include FDA User Fee.

Est. Cost of Project: $25,000

513(g) Request

Two pathways available:

Est. Cost of Project:

Option 1: 510(k) Pathway without additional documents.

Option 1: $3,500

Option 2: De Novo with additional documents.

Option 2: $6,500

Does not include FDA User Fee.

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Breakthrough Device Designation

Submission is nearly identical for Breakthrough and STeP.
If BDD is denied, we are willing to revise and resubmit.
Does not include FDA User Fee

Est. Cost of Project: $5,000

Regulatory Pathway, Predicate ID, & Testing Plan

For FDA Submissions.
Typically only needed when there is no FDA Special Controls Guidance or if device is significantly different from cleared devices.
Does not include FDA User Fee.

Est. Cost of Project: $1,500

Usability Engineering File

Define User Group, Use Environment, & User Interface.
ID of Use Errors (including task analysis).
Critical Task Analysis.
Creation of User-Related Risk Analysis (URRA).
Creation of Summative Usability Test Protocol.
IFU Development.
Does not include FDA User Fee.

Est. Cost of Project: Please Contact Us

US Agent Services

Includes Initial FDA Registration.

Does not include FDA User Fee.

Initial Registrations: $800

Annual Renewals: $600