ADB Consulting & CRO Inc.
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FY2026 FDA 510(k) Budget Planner

Use this worksheet to organize the major cost categories in a 510(k) submission budget. Figures below reflect FDA's published FY2026 fee where available and typical third-party cost categories. Confirm current FDA fee amounts and your own vendor quotes before finalizing a budget — this planner is for organization purposes and does not constitute regulatory advice or a cost estimate for any specific device.

Section A — FDA Fees (FY2026)

FDA Establishment Registration Annual Fee (FY2026): $11,423

FDA 510(k) Premarket Notification (MDUFA) User Fee: fee amount is set annually by FDA and updates each October — review FDA's current MDUFA fee schedule directly at fda.gov before budgeting this line. A reduced rate is available for FDA-certified small businesses; eligibility and current rates are confirmed on the same FDA schedule.

Section B — Typical Third-Party Cost Categories

These vary significantly by device type, risk classification, and applicable consensus standards — treat each as a line to quote, not a fixed figure:

- Bench / performance testing (device-specific standards)
- Biocompatibility testing (per ISO 10993, if applicable)
- Software and cybersecurity documentation/testing (if the device is software-containing or connected)
- Sterilization validation (if the device is sterile)
- Electrical safety and EMC testing (if applicable)
- Clinical data collection (if required for the chosen pathway)
- Labeling and IFU development

Section C — ADB's Published Flat-Fee Tiers

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- 510(k) Readiness & Gap Assessment — $4,950 flat fee
- Pre-Submission (Q-Sub) Preparation — $4,500 flat fee
- Full 510(k) Submission Package Preparation — from $24,500 (invoiced)
- The Gap Assessment fee is credited 100% toward Full Submission Package Preparation if engaged within 90 days.

ADB does not conduct testing or generate test data — all source test data, reports, and performance documentation are client-provided inputs. ADB reviews those inputs and prepares submission documentation.

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Your Budget Worksheet

Fill in an estimated cost and, as you receive vendor/consultant quotes, your actual quoted number.

Cost Category	Estimated Cost	Actual Quote	Notes
FDA Establishment Registration Fee			
FDA 510(k) (MDUFA) User Fee			
Bench / Performance Testing			
Biocompatibility Testing			
Software / Cybersecurity Documentation			
Sterilization Validation			
Electrical Safety & EMC Testing			
Clinical Data Collection			
Labeling & IFU Development			
Regulatory / Consulting Support			
Contingency (recommended 10–15%)			
TOTAL			

Fee figures current as of FY2026 — review
budgeting organization only. It does not cons
outcome. ADB Consulting & CRO Inc. — ad