

510(k) Submission Checklist:

Key Steps for FDA Clearance

Regulatory & Strategy Planning

- Confirm device classification (Class I, II, or III)
- Determine if a 510(k) is required
- Identify suitable predicate device(s)
- Choose submission type: Traditional, Special, or Abbreviated
- Develop regulatory strategy (US market, testing needs, etc.)



Preclinical Testing & Performance Data

- Conduct necessary bench testing (mechanical, electrical, etc.)
- Perform biocompatibility testing (if applicable)
- Complete sterilization validation (if applicable)
- Prepare software validation (if software is part of the device)



Required 510(k) Documentation

- Cover letter & FDA 510(k) submission form (Form 3514)
- Indications for Use statement (Form 3881)
- 510(k) Summary or Statement
- Device Description
- Substantial Equivalence Comparison
- Risk Management Report (per ISO 14971)
- Labeling and IFU (Instructions for Use)
- Sterilization & Shelf-life data (if applicable)
- Summary of Performance Testing
- Software Documentation (if applicable)
- Declaration of Conformity (e.g., IEC standards)



Submission & FDA Communication

- Format documentation using FDA's eSTAR template
- Submit via FDA's CDRH portal or eCopy
- Respond to FDA requests for additional information (AI letter)
- Track review status and expected clearance timeline



Post-Submission Preparation

- Prepare for labeling updates or minor modifications
- Plan post-market surveillance (PMS) activities
- Train marketing & sales teams on cleared indications

