

FDA Premarket Submission Documentation Checklist



1. Administrative Information

- Cover letter and submission type (510(k), De Novo, or PMA)
- Applicant, manufacturer and US agent details
- Device name, model, and classification information
- Table of contents and document organization



2. Device Description & Intended Use

- Device description, principles of operation and key specifications
- Indications for use and intended user / use environment
- Comparison with predicate device (if applicable)
- Accessories, software, and variants



3. Performance Testing & Evidence

- Non-clinical testing (bench, electrical, mechanical, etc.)
- Software validation and cybersecurity testing (if applicable)
- Biocompatibility, sterilization and shelf-life (if applicable)
- Clinical evidence (when required)



4. Risk Management

- Risk analysis and risk control measures (ISO 14971)
- Residual risk evaluation and risk acceptability
- Risk-related testing and verification activities
- Summary of risk management activities



5. Labeling & Packaging

- Device labeling (e.g., Instructions for Use)
- Warnings, precautions and contraindications
- Packaging information
- UDI requirements (if applicable)



6. Submission Preparation

- Compilation and formatting per FDA guidance
- eCopy and electronic submission requirements
- Administrative forms and declarations
- Internal review and readiness assessment