

FDA 510(k) RTA Compliance Checklist – Avoid Submission Rejection

General Submission Structure

- Cover letter with contact info and submission summary
- FDA 510(k) summary or statement and signed Truthful & Accuracy statement
- User Fee form (FDA 3601) as proof of payment

Predicate Comparison & Intended Use

- Predicate device clearly stated with 510(k) number
- Substantial equivalence section completed
- Device labeling consistent with intended use

Performance & Technical Documentation

- Test reports included for performance, electrical safety, EMC
- Software documentation per FDA guidance (if applicable)
- Biocompatibility, sterilization, and shelf-life data included

Formatting & Admin Checks

- Device images, schematics, and diagrams labeled properly
- RTA checklist reviewed and self-assessment completed