

FDA RTA Readiness Checklist for 510(k) Submissions

What's Inside:

- FDA's RTA timeline: 15-day review → 180-day response window
- Administrative vs Substantive review differences
- Pre-submission document prep
- eSTAR formatting guide

Required components checklist:

- Table of Contents
- Device Description
- Administrative Information (eg., FDA Form 3514, contact details)
- Predicate Comparison Table
- Labeling Samples
- Sterilization/Packaging Info (if applicable)
- Shelf Life and Biocompatibility Info (if applicable)
- Test Data Summary
- Truthful & Accurate Statement
- UDI & SBOM info (for SaMDs)

Links to:

- [FDA RTA Guidance](#)
- [eSTAR Resources](#)

Bonus: Tips from Regulatory Experts at Elexes