Elexes

510(k) Submission Preparation Checklist: FDA Clearance Essentials

Device Classification & Predicate

- Product code and regulation number identified
- Device class confirmed (Class I exempt, II, III)
- Predicate selected and substantial equivalence mapped

Core Documentation Prepared

- Truthful & Accuracy Statement
- Indications for Use (IFU)
- Device Description and Technological Characteristics
- Comparison to Predicate Table
- Labeling and Instructions for Use

Testing and Performance Evidence

- Bench testing (mechanical, electrical, etc.)
- Biocompatibility and sterilization validation (if applicable)
- EMC, wireless, or software verification/validation
- Shelf-life and packaging validation reports

Submission Formatting

- All sections bookmarked and paginated
- eCopy or eSTAR format followed
- Table of Contents and submission cover letter included
- PDF optimization for size and accessibility