Elexes

FDA 510(k) Clearance Readiness Checklist – Avoid Delays, Accelerate Approval

Submission Planning

- Device classification and product code confirmed
- Predicate selected and substantial equivalence established
- FDA guidance documents reviewed

Documentation Prepared

- Truthful & Accuracy statement
- Indications for Use statement
- Device description and technological comparison
- Predicate comparison table
- Bench, biocompatibility, or software validation reports (as applicable)

Submission Format

- RTA checklist followed line-by-line
- eSTAR template used (if available)
- Table of contents, pagination, bookmarks included

Final Checks

- Labeling, Instructions for Use (IFU), and Unique Device Identifier (UDI) formatted and submitted
- Internal QA review of attachments to the eSTAR