Elexes

510(k) Submission Readiness Checklist — 2025 FDA Update Edition

General Readiness:

- Regulatory team briefed on 2025 FDA eSTAR and FDA eCopy changes
- Submission template converted to eSTAR format
- Old templates and eCopy tools archived

Testing & Documentation:

- Performance testing results validated per updated FDA guidance
- Biocompatibility and software documentation formatted for eSTAR
- Labeling, UDI, and IFU sections updated

Formatting & Cross-Referencing:

- Table of Contents and section IDs matched to FDA structure
- Cross-references embedded and hyperlinked where applicable
- PDF validation passed (PDF/A format compliance)

Final Review:

- Submission reviewed using FDA eSTAR Preview Tool
- Q-sub (if needed) completed prior to submission
- Submission planned 60–90 days before target market entry