Elexes

FDA PMA Submission Readiness Checklist: What You Need to Prepare

1. Regulatory Readiness

- Device classified as Class III (no predicate exists)
- Confirmed that indications for use are specific and not general
- Manufacturing information is known

2. Technical Documentation

- Nonclinical testing results (bench, biocompatibility, etc.)
- Clinical investigation protocol and outcomes
- Manufacturing site info and QMS conformance
- Labeling and Instructions for Use (IFU)
- Risk Analysis documentation

3. Application Strategy

- Decide PMA type: Traditional / Modular / PDP / HDE
- Plan for pre-submission meeting with FDA
- Prepare for Day-100 meeting and panel review
- Draft summary of safety and effectiveness data (SSED)

4. Post-Submission Preparation

- Develop post-approval study plan (if needed)
- Assign regulatory contact for FDA queries
- Plan for postmarket reporting and updates