Elexes

PMA Checklist

Confirm Eligibility

- Is the device Class III with no predicate?
- Have you checked FDA's Class III device list?
- Did you complete a pre-submission meeting with FDA?

Prepare Core Documents

- Cover letter & FDA Form 3514
- Financial Disclosure Statement
- Clear Table of Contents

Device Description & Labeling

- Device name, model, and description
- Summary of technological features
- Draft Instructions for Use (IFU) and labels

Nonclinical Testing

- Biocompatibility and bench testing
- Electrical safety, EMC, and software validation
- Sterilization and shelf-life data

Clinical Evidence

- IDE and IRB approvals (if applicable)
- Final clinical study report
- Risk/benefit and adverse event analysis

Manufacturing & Quality Systems

- Facility overview & process controls
- QMS compliance with 21 CFR Part 820

Environmental & Labeling Compliance

- Environmental Assessment or Exclusion
- UDI strategy and claims substantiation

Assemble & Submit

- eCopy compliant with FDA format
- User fee payment and confirmation
- Submit and track FDA response