

FDA PMA Submission Checklist – Class III Device Approval Guide

Strategic Planning

- Understand the PMA requirement and confirm its applicability to the product
- Assemble a cross-functional team including regulatory, quality, and manufacturing experts.
- Conduct a gap analysis against the FDA's submission requirements
- Identify the milestones and develop the detailed project timeline
- Use pre-submission to clarify any outstanding questions about the submission and related documents
- Design and execute pre-clinical and clinical studies as needed.

PMA Submission Contents

- Complete device description with intended use
- Compile labelling
- Ensure robust data collection and documentation of clinical and non-clinical data
- Labeling and Instructions for Use (IFU) aligned with indication
- Manufacturing, sterilization, and shelf-life information
- Summary of safety, effectiveness, and performance data
- Risk Management file
- Financial disclosure statements

Administrative & Compliance Documents

- Cover letter and FDA Form 3514
- Truthful and accurate statement signed by a responsible official