FDA PMA Submission Checklist for Medical Devices

Regulatory & Strategic Planning

- Confirm Class III classification
- Determine PMA submission type (traditional or modular)
- Identify need for IDE and/or Pre-Submission meeting with FDA

Documentation & Testing

- Compile Design History File (DHF) and risk analysis
- Complete non-clinical testing (bench, biocompatibility, software validation)
- Plan and execute clinical study or provide valid clinical evidence

Labeling & Manufacturing

- Finalize labeling, Instructions for Use (IFU), and promotional materials
- Provide manufacturing details and confirm QMS compliance

Submission & Post-Approval

- Prepare and submit PMA application and FDA eCopy
- Respond to FDA questions or Advisory Panel input (if needed)
- Plan for post-approval studies and reporting