Regulatory Overview – PMA

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Overview

• What is a PMA?
• What is the PMA review process?
• What types of PMA Supplements are there?
• What key factors should be considered for PMA submissions?
PMA

• Regulatory submission required for Class III devices

• Class III - devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices and

• Such devices are:
  – life sustaining or life supporting
  – substantial importance in preventing impairment of human health; or
  – present unreasonable risk of illness or injury
Class III Devices

- Not Substantially Equivalent Post Amendment Devices
- Regulated As New Drugs Before May 28, 1976
- Class III preamendment devices which, by regulation in 21 CFR, require a premarket approval application.
PreSubmissions

• Early Interaction

• Prior to starting a study or submitting an application (IDE/510(k)/PMA)

• Get major issues addressed/requirements clarified upfront

• PreSubmission package sent in with relevant information and specific questions
PreSubmission Meeting

- Content and format of PMA submission
- Presentation of data (clinical & key non clinical)
- Additional analyses or testing needed to address changes made to device or protocol during the IDE study
- Analyses specific to inclusion of foreign data
- Plans to address “future PMA concerns”
- Special data requests for statisticians, BIMO
- Potential for postapproval study, or if already planned, outline of postapproval study protocol
PMA

• Original - New indication or changes result in a new device; new pre-clinical and new clinical data

  – Traditional - Submit complete PMA (pre-clinical, clinical, manufacturing) at one time

  – Modular - Submit PMA in pieces: clinical data not finalized; however, pre-clinical, manufacturing, etc., could be submitted as separate modules for review and acceptance
PMA Review Process

- Acceptance/Filing review
- Substantive review
- Formal and informal interactions
- Advisory panel review, if needed
- Closeout
- Approval
PMA Review

• Acceptance/Filing review and decision
  – Determine whether information provided is complete to allow for substantive review
  – Within 45 days of receipt of PMA, as required by regs (21 CFR 814.42(a))

• Substantive or In depth team review
PMA Review Team

- Team Leader/Lead Reviewer (ODE)
- Clinical (ODE)
- Statistical (OSB)
- Preclinical Animal Studies (ODE or OSEL)
- Engineering (ODE or OSEL)
- Biocompatibility (ODE or OSEL)
- Software (ODE or OSEL)
- Microbiology (ODE)
- Quality Systems and Manufacturing (OC)
- Bioresearch Monitoring (OC)
- Patient Labeling (OCER)
- Epidemiology (OSB)
- Combination Products (CBER or CDER)
Interactions: Communication

• When
  – Throughout the review cycle
  – Close to target deadlines

• How
  – Letter
  – Email
  – Phone
  – Fax
Advisory Panel Review

- Independent panel of experts
- Panel members include: clinicians, statisticians, and representatives from academia, industry, and consumer advocacy groups
- Provide recommendations regarding approvability of the device, conditions of approval, and labeling
- Open to the public
PMA Closeout

• Labeling

• Summary of Safety & Effectiveness Document (SSED)

• Post-approval study
Approval

- Decision Based on FDA Review, Panel Recommendation, and GMP and Bioresearch Monitoring Inspections

- Approval Order = Go to Market

- Federal Register Notice of Approval Decision
  - Availability of Approval Order, Labeling, and SSED
Conditions of Approval

• General conditions, for example:
  – Mandatory annual reporting
  – Restrictions on advertising claims
  – Mandatory reporting of adverse events (MDR) - [www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) and product defects and failures (recalls) - [www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm)
  – Submission of PMA supplements for changes to the device (e.g., design, manufacturing, or labeling)

• Specific conditions, for example:
  – Specific reporting requirements
  – Post-approval studies
Changes After Approval
PMA Supplements

- Panel Track Supplement
- 180 Day Supplements
  - Traditional
  - Site change
- Real-Time Supplement
- Special PMA Supplement – Changes Being Effected
- 30 Day Notice/135 Day PMA Supplement
Important Links

• PMA Modifications Guidance Document

• Device Advice -
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

• CDRH Guidance Document search
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

• A-Z index: http://www.fda.gov/SiteIndex/default.htm
The Big Picture

• Ultimate goal is approval of safe and effective devices
• Interactive review can improve efficiency; be prepared to be responsive and communicative, and to fulfill your commitments to respond to questions
• A well-organized PMA submission can help streamline the review. Make it easy to find the info we need in your extensive documentation.
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Thank You

Questions?