# 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

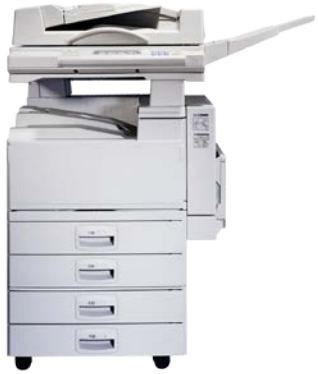
- Acceptance/Filing review and decision
  - Determine whether information provided is complete to allow for substantive review
  - Within 45 days of receipt of PMA, as required by regs (21 CFR 814.42(a))
- Substantive or In depth team review

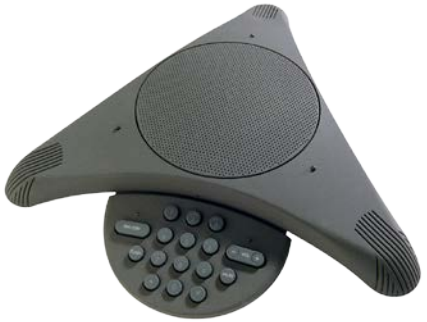
# PMA Review Team

- 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 and product defects and failures (recalls) - 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

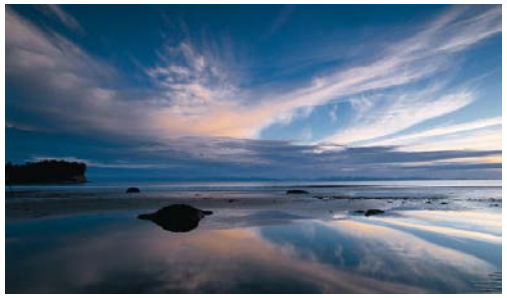
# Changes After Approval PMA Supplements

- 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
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089274.htm
- 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.

# PMA Staff

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  - Laura Byrd, Lisa Fisher, Donna Headlee, Wanda Sawyer-Major, Ed Webman
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# Thank You

Questions?