The FDA PMA Process for *In Vitro* Diagnostic Devices

FDA/Center for Devices and Radiological Health/Office of *In Vitro* Diagnostics

April 17, 2012

What is the PMA Review Process?

Presented by

Kelly A. Wilkicki, M.P.P.

Policy Analyst

Office of the Director/OIVD

Presentation Overview

- Medical device marketing applications
- Types of premarket applications (PMAs)
- Types of PMA supplements and notices

Marketing Applications

- 510(k)
  - De Novo
- PMA (PreMarket Approval)
  - Traditional PMA
  - Modular PMA

Traditional PMAs

- Required elements can be found in 21 CFR 814 and section 515 of the Food Drug & Cosmetic Act
- Also need a user fee and six copies of the entire PMA (one should be electronic)

Traditional PMAs

Review process

- Filing meeting and decision (within 45 days)
- Major deficiency letter (within 90 days)
- 100 day meeting (if needed/requested)
- Panel meeting (only if needed)
- Approval, Approvable, Not Approvable (within 180 days, MDUFA Goal)

GMP review is also conducted by OIVD

- GMP deficiency letter
- Inspection

Modular PMAs

- Complete contents of a PMA are broken down into sections or "modules," such as preclinical, clinical, manufacturing, that together become a complete application
- No inspections until the final module is submitted
- User fee is required by the time the first module is received
- Each module has a 90 day review clock

(particularly good for BiMo and Mfg sections)

Post Approval

Conditions of Approval:

- Annual reports
- Post approval studies (if needed)

Final printed labeling

Recall and medical device reporting (MDRs)

Changes to the device typically require PMA supplements