Hogan Lovells

ClinicalTrials.gov

Association of Medical Diagnostics Manufacturers
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Overview

- History
- Types of Trials
- Basic Requirements
- Registering
- Reporting Results
- Certification

History of Clinical Trial Registry

- Food and Drug Administration Modernization Act of 1997 (FDAMA)
  - Applies to Drugs
  - "Applicable Clinical Trial" (PHS Act § 402(j); FDC Act § 505)
- Clinicaltrials.gov launched in February 2000
- Food and Drug Administration Amendments Act of 2007 (FDAAA)
  - Extends to Devices
  - "Applicable Device Clinical Trial" (FDC Act § 522)

Types of Trials

- Applies to *In Vitro* Diagnostic (IVDs) devices and other devices
- "Applicable Device Clinical Trial"
  - "…a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the [FDC Act] against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and a pediatric postmarket surveillance as required under [FDC Act § 522]."

Types of Trials

- “For example, a study of a diagnostic device (such as an in vitro diagnostic (IVD) in which the primary purpose is to evaluate the ability of the device to make a diagnosis of a disease or condition is directly related to human health, and therefore, would be considered a study of health outcomes for [these] purposes . . . .”

  http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

Types of Trials

- Required if Clinical Trial:
  - Supports a Premarket Approval (PMA) Application
  - Supports a 510(k) Premarket Notification
  - Supports a Humanitarian Device Exemption (HDE) Application
  - Under an Investigational Device Exemptions (IDE)
  - Of a Previously Cleared/Approved Device
  - US or OUS
  - Manufactured in US (then exported) & would require 510(k), PMA, or HDE in US
- Required if:
  - Section 522 Pediatric Postmarket Surveillance

Types of Trials

- Exemptions:
  - Retrospective
  - De-identified human specimens
  - Small Feasibility Studies

Basic Requirements

- Disclose information on clinical trials to NIH
- Posted on publicly accessible website (www.clinicaltrials.gov)
- Trial details available on website include:
  - Goals
  - Conduct
  - Recruitment
  - Contact Information

Registering

- Within 21 days after first patient enrolled
- Special rules if trial initiated before September 27, 2007
  - If ongoing on September 27, 2007 and completed before December 26, 2007, registration not required

Results: Basic Results

- Submitted after device cleared/approved
- 1 Year after estimated/actual trial completion
- Extension possible with good cause request
- For cleared/approved devices
- Includes:
  - Demographic/baseline characteristics
  - Primary & secondary outcomes
  - Point of contact
  - Information on certain agreements with principal investigators

Results: Additional Detail

- More detailed information could be required once implementing regulations are promulgated
  - Summary of results, both non-technical and technical versions
  - Information on the study protocol
- Regulations will specify whether required for both approved/cleared and unapproved/uncleared products, or only for approved/cleared products
- Regulations would also specify whether this additional information would be required within 1 year or 18 months

Certification Requirement

- Purpose is to provide means for ensuring that public has access to clinical trial information
- Certification Required with PMA, 510(k), HDE Submissions
  - Certification Requirement Effective as of December 2007
  - FDA Form 3674 available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm048364.pdf

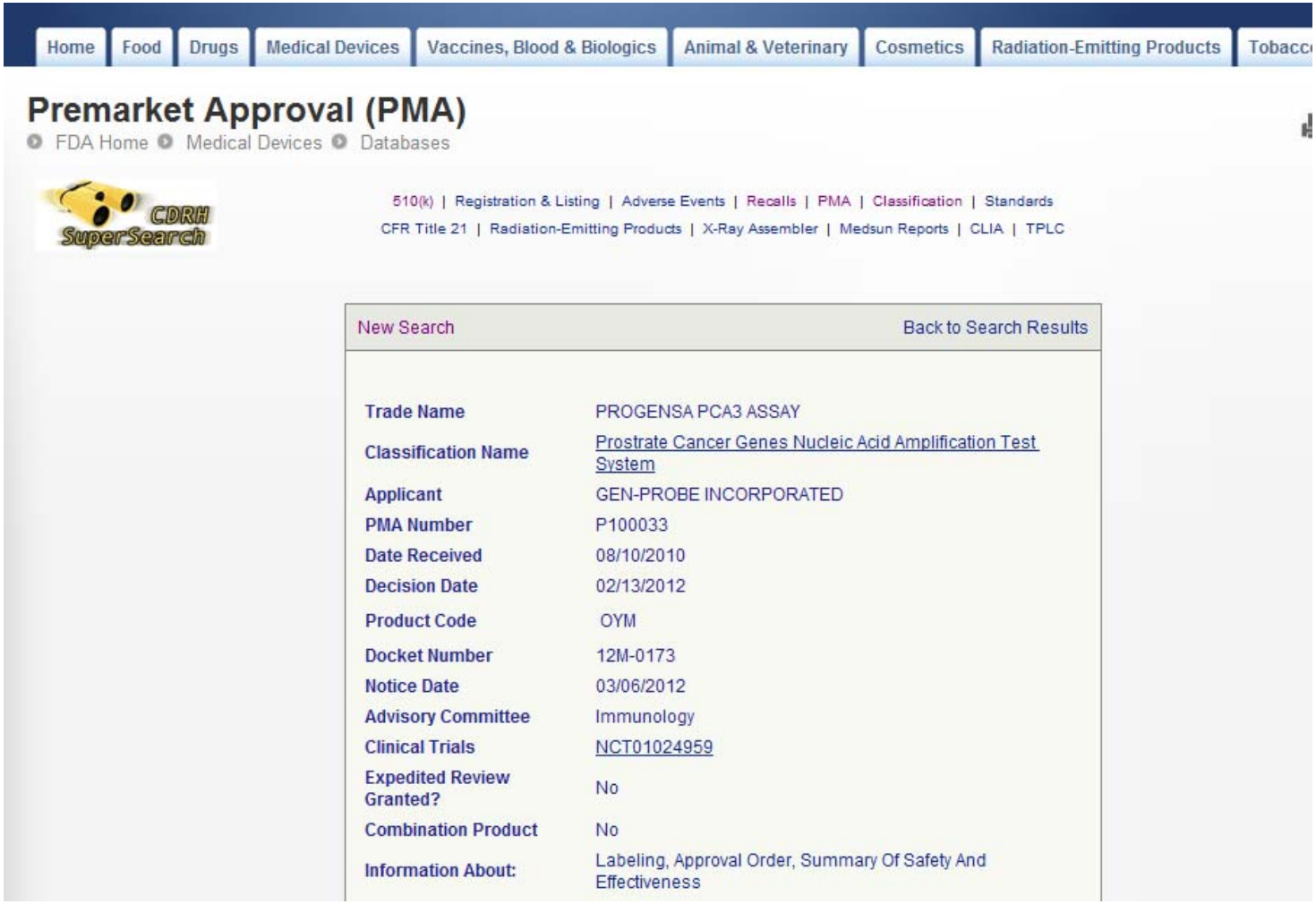
FDA Guidance

- *Certification To Accompany Drug, Biologic Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added by Title VIII of The Food and Drug Administration Act (January 2009)*
- Available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM164819.pdf

IVD Study Example

- Recently Approved Gen-Probe Progensa PCA3 Assay for Prostate Cancer Genes (P100033)
  - ClinicalTrials.gov Identifier: NCT01024959
  - Study Type: Interventional
  - Study Design: Intervention Model: Single Group Assignment
  - Masking: Open Label
  - Primary Purpose: Diagnostic
  - Official Title: Clinical Evaluation of the PROGENSA(R) PCA3 Assay in Men With a Previous Negative Biopsy Result

Sample FDA Webpage



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Premarket Approval (PMA)

FDA Home ▸ Medical Devices ▸ Databases

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

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Trade Name	PROGENSA PCA3 ASSAY
Classification Name	Prostrate Cancer Genes Nucleic Acid Amplification Test System
Applicant	GEN-PROBE INCORPORATED
PMA Number	P100033
Date Received	08/10/2010
Decision Date	02/13/2012
Product Code	OYM
Docket Number	12M-0173
Notice Date	03/06/2012
Advisory Committee	Immunology
Clinical Trials	NCT01024959
Expedited Review Granted?	No
Combination Product	No
Information About:	Labeling, Approval Order, Summary Of Safety And Effectiveness

Summary

- Complex, evolving law
- ClinicalTrials.gov can apply to IVD clinical trials
- Exemption for de-identified human specimens
- Certification required for 510(k) clearance or PMA approval

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