Regulatory Submissions: IDEs and HDEs

Lynn Henley, M.S., M.B.A.

Investigational Device Exemptions and Humanitarian Device Exemptions Programs

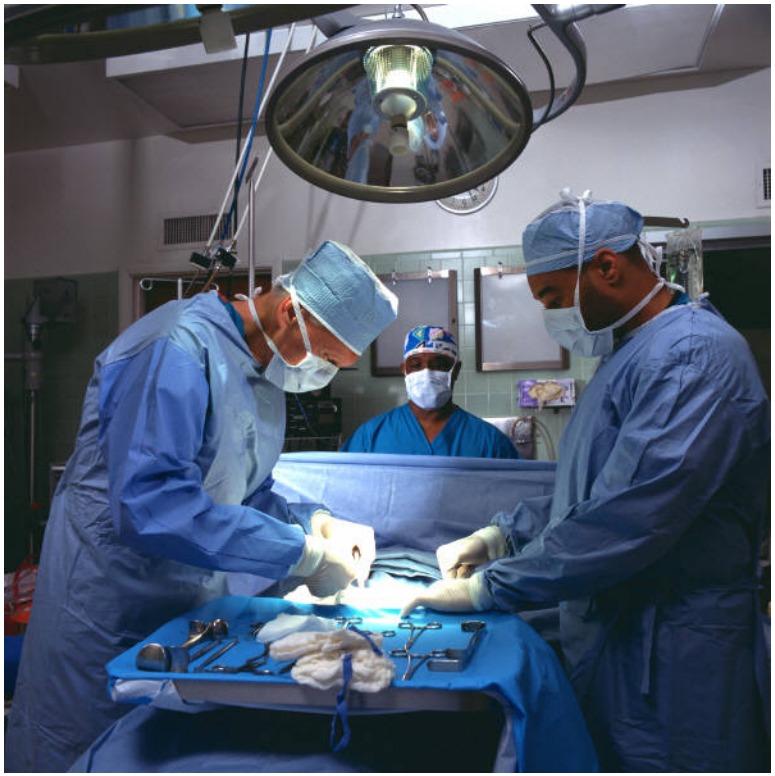
Office of Device Evaluation

Center for Devices and Radiological Health, FDA

Overview

- Definition
- Device Classification
- Types of Submissions
- Investigational Device Exemptions (IDEs)
- Pre-Submissions
- Humanitarian Use Devices (HUDs) and Humanitarian Device Exemptions (HDEs)

Medical Devices



Definition

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article, including any component, part, or accessory which is:
  - Recognized in the official National Formulary, or the United States pharmacopeia, or any supplement to them
  - Intended for use in the **diagnosis of disease or conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals**
  - Intended to affect the structure or any function of the body of man or other animals
- Which does **NOT achieve it primary intended purposes through chemical action within or on the body** of man or other animals and which is **NOT dependent upon being metabolized for the achievement of its intended purposes.**

Device Classification

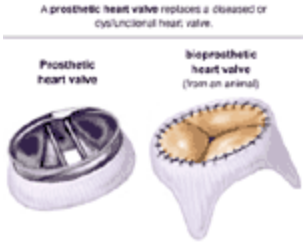
Risk-Based Paradigm

Medical devices are classified and regulated according to their degree of risk to the public

Class I (low risk)

Class II

Class III (high risk)



Types of CDRH Submissions

- Investigational Device Exemption (IDE)
- Premarket Notification Submission [510(k)]
- Premarket Approval Submission (PMA)
- Humanitarian Device Exemption (HDE)

Investigational Device Exemption (IDE)

An approved Investigational Device Exemption (IDE) allows:

- an investigational device to be used in a clinical study in order to collect data required to support a Premarket Notification [510(k)] submission, a Premarket Approval (PMA) application, or a Humanitarian Device Exemption (HDE) submission
- a device to be shipped lawfully for the purpose of conducting investigations

510(k) Clearance

- "Substantially equivalent" to predicate device
  - Same as device currently marketed
- Established in 1976 with the medical device amendments
- Majority of all devices are marketed via 510(k)s
- Mostly Class I and II, few Class III devices
- 510(k) is a **clearance**
  - Permits marketing/commercialization in U.S.

PMA (Pre-Market Approval)

- Required process of scientific review to ensure the reasonable **safety and effectiveness** of medical devices using valid scientific evidence

- FDA approval required before the device can be legally marketed

HUDs and HDEs

- Humanitarian Use Device (HUD)
- Humanitarian Device Exemption (HDE)
  - Office of Orphan Products Development designates HUD
  - Intended to treat a disease or condition affecting fewer than 4,000 individuals in the US per year
  - No comparable device available
  - CDRH reviews HDE

Investigational Device Exemptions (IDEs)

Regulatory Requirements for Clinical Studies of Medical Devices

- Informed Consent and Human Subject Protections (21 CFR Part 50)
- Institutional Review Board oversight (21 CFR Part 56)
- Financial Disclosure (21 CFR Part 54)
- Investigational Device Exemption (IDE) application (21 CFR Part 812)

Types of Studies

- Significant Risk - a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject – e.g., an implanted device

- Non-Significant Risk - the sponsor makes the initial determination of SR or NSR, then the IRB makes a determination

- Exempt from IDE

Pre-Submissions

- Also known as a Pre-IDE or a Study Determination Inquiry
- If a sponsor or Investigational Review Board (IRB) is uncertain whether a study is exempt, significant risk or non-significant risk, FDA will make a determination
- Brief protocol, device description, and a description of intended population
- FDA will issue a letter; the determination is final

Pre-Submissions (continued)

- Meet early and often

- "Draft Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff" issued July 13, 2012

Humanitarian Use Devices (HUDs) and Humanitarian Device Exemptions (HDEs)

Section 520(m) of the Food, Drug and Cosmetic Act

"… to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States." [yearly]

Purpose of HDE Provisions

Provide incentive for development of devices intended for treatment or diagnosis, **in small patient populations where otherwise a device manufacturer's research and development costs could exceed market returns**

HDE vs. PMA

- Both are marketing approvals
- Both subject to post-market Medical Device Reporting (MDR) requirements
- Approval thresholds differ:
  - PMA: safety and **effectiveness**
  - HDE: safety and **probable benefit**

List of Approved HDEs

- 56 approved HDEs since 1996*
- List of approved HDEs and their Summaries of Safety and Probable Benefit (SSPB) available at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm#2

Contact Information

Division of Small Manufacturers, Consumer and International Assistance (DSMICA)

1-800-638-2041

301-796-7100

dsmica@fda.hhs.gov