Regulatory Issues in Medical Device Development

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Topics Covered in the Presentation

- Device Classes
- Identification of Some Terms
- Global Perspectives for Device Approval
  - United States
  - European Union
  - China
  - Russia

Regulatory Classification of Devices

- Class I – low risk (~5% will require a 501K)
  - subject to general controls (published standards for labeling, manufacturing, post-marketing surveillance and reporting
  - reasonable assurance that general controls alone are sufficient to assure safety and effectiveness
  - formal FDA review not required for most devices prior to market introduction
  - Examples – tongue depressor, handheld surgical instruments

Regulatory Classification of Devices

- Class II – medium risk
  - general controls alone insufficient to provide reasonable assurance of safety and effectiveness
  - adequate information available to establish special controls (performance standards, design controls, post-market surveillance programs)
  - Most require pre-market notification (PMA or 510(k)) before market introduction
  - Examples – infusion pump, surgical drapes

Regulatory Classification of Devices

- Class III – high risk
  - devices are life-sustaining or supporting, of substantial importance in preventing impairment of human health or present high risk or illness or injury
  - general and special controls inadequate to provide reasonable assurance of safety and effectiveness
  - most require clinical data and PMA approval prior to market introduction
  - Example – implantable pacemaker

Quality System Regulation (QSR) 21 CFR Part 820

- = Good Manufacturing Practice
- Specifies Quality Management System requirements for device manufacturers.
- FDA conducts random inspections to determine compliance with 21 CFR part 820

US FDA 510K Premarket Notification

- Most Class II devices must obtain 510(k) clearance from the FDA
- Requires that you demonstrate that your device is safe and effective by proving substantial equivalence to a legally marketed device (predicate device).

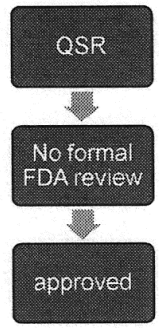
PMA – Premarket Approval 21 CFR Part 814

- (c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:
- (1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or
- (2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or
- (3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

US FDA 510K Premarket Notification

- Each person who wants to market in the United States, a class I, II, or III device intended for human use, for which a PMA is not required, must submit a 510(k) to FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements of the Federal Food Drug, and Cosmetic Act (the act) and does not exceed the limitations of exemptions in xxx.9 of the device classification regulation chapters (e.g., 862.9, 864.9).
- There is no specific 510(k) form. However, 21 CFR 807 Subpart E describes requirements for a 510(k)submission.

Class I – low risk

- 

Investigational Device Exemption (IDE) – 21 CFR Part 812

- IDE submission is required for Class III devices as well as some Class II devices
- provides approval to perform device clinical trials
- Allows sponsor to lawfully transport investigational devices

Class II – medium risk

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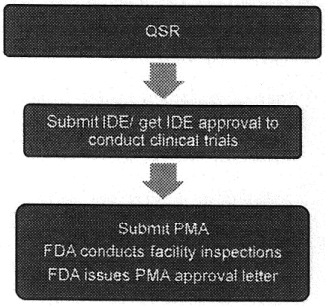
Class III – high risk

- 

Medical Device Classes - Russia

- The Russian approval process is based on product testing, regardless of whether your medical device has been tested and certified to international standards.
- Russia does not recognize European CE Marking, US FDA 510(k) clearance or any other approval from a national Ministry of Health (may require device to have approval in your home market.

Medical Device Classes - EU

- Class I (non-sterile, non-measuring)
- Class I (sterile, measuring)
- Class IIa
- Class IIb
- Class III

- These are just a few examples of the intricacies of global medical device development.

Medical Device Classes - China

- Class II devices in the US might be classified as Class III devices in China.
- Clinical trials may have to be conducted for Class II/III devices that do not already have approval elsewhere
- Long-term implantable devices require the conduct of clinical trials in China regardless of whether trials have already been conducted elsewhere in the world