FDA Regulation and Risk Assessment of Medical Devices

IOM Workshop on the Certification of Personal Protective Technologies
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Markham C. Luke, MD PhD
Deputy Office Director & Chief Medical Officer
Office of Device Evaluation, CDRH, FDA
Office of Device Evaluation – Who are we?

- 380+ dedicated public health officials
- Engineers, scientists, clinicians, and support staff
- Organized into seven divisions: five by clinical speciality, and two for support
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*Acting
IOM: What current process is used at FDA to assess the level of risk of a medical device and make determinations about the device class and whether the 510(k) process is required?
Risk-Based Paradigm

The law gives us the flexibility to calibrate our regulatory approach to the level of potential risk posed by new products.
Risk-Based Classification of Medical Devices

- Class I: simple, low risk devices
  - Subject to “General Controls”
    - Registration and Listing, Quality System, Adverse Event Reporting, Prohibitions against misbranding and adulteration
  - Most exempt from premarket review
Risk-Based Classification of Medical Devices

- **Class II**: more complex, higher risk
  - Subject to General Controls PLUS Special Controls
  - Most require Premarket Notification [510(k)]
  - Regulatory standard is “Substantial Equivalence”
  - Most cleared based on preclinical and animal testing (10% require clinical)
Substantial Equivalence (SE)

- 510(k) submissions compare new devices to “predicate” marketed devices
- A decision flowsheet results in a binary determination of SE vs. NSE
  - Indication and Intended Clinical Effect/Use
  - Technological Characteristics (Design/Material)
  - New types of Safety/Effectiveness Concerns
  - Performance Data
Risk-Based Classification of Medical Devices

• Class III: most complex, highest risk
  – Bench – Animal - Clinical
  – Premarket Application [PMA]
  – Regulatory standard is “reasonable assurance of safety and effectiveness”
  – May include post-approval study requirements
Humanitarian Device Exemptions

- Devices targeted at fewer than 4000 patients per year
- Must demonstrate safety and probable benefit outweighs probable risk
IDE (Investigational Devices Exemption)

- Allows investigational devices to be used in clinical studies to support PMA, 510(k)
- Requirements for informed consent, labeling, monitoring, records/reports
- Requires approval by Institutional Review Board (IRB) and, for significant risk devices, FDA
- 30-day review period
Combination Products

- Include device/drug and device/biologic products that are:
  - physically linked; or
  - separately packaged together (e.g., drug and device products); or
  - packaged separately but required to be used together.

- Raise unique regulatory and scientific issues
IOM: Are medical device determinations predominantly based on risk to the patient or the healthcare worker or both?
Medical Device Risk to Patient and Provider

- Risk is assessed for medical devices in the setting of risk vs. benefit
- Risk to the healthcare provider is considered during the review of a medical product and steps are taken to minimize risk. Examples:
  - Eyewear protection for lasers
  - Universal precautions
  - Latex and other allergenicity concerns
IOM: What are the current post-marketing surveillance efforts for device safety?
Medical Device Post-marketing Surveillance

- MedWatch – FDA Safety Information and Adverse Event Reporting Program
- MedSun – Medical Product Safety Network
- MAUDE – Manufacturer and User Facility Device Experience
- Quality Systems
- Post-approval Studies
IOM: Are any medical devices required to go through third-party testing prior to FDA clearance?
Testing Prior to Marketing

- Non-clinical testing
  - Bench testing
  - Non-clinical models
- Clinical testing
- Requirements can be described in regulations, guidance or in meetings with FDA
- Standards and certifications
Reliance on third-party certification

• FDA may allow medical device labeling to include description of certification by a third party.

• An example is for N95 respirators – FDA describes in the 510(k) Guidance for Surgical Masks that labeling can include mention of N95 certification by NIOSH if the device has such certification.
Standards and conformity

• FDA shall accept a declaration of conformity unless:
  – the data or information submitted to support the declaration does not demonstrate that the device is in conformance with the standard; or
  – the standard identified in the declaration is not applicable to device under review.
IOM: How are devices (e.g. gowns) regulated that are sold without having gone through the FDA medical device clearance process?
Regulation of Exempt Devices

- Most Class I devices are exempt from notification
- General Controls
  - Prohibition against adulterated or misbranded devices
  - GMPs, registration of manufacturing facilities
  - Listing of devices types
  - Record keeping
  - Repair, replacement, refund
Regulation of Exempt Devices

- Post-market surveillance
  - Evaluation of claims made
  - Manufacturing defects
  - Adverse event reports

- Compliance actions
FDA and Risk-based Device Regulation – Take Aways

• Protective medical device equipment related to the treatment, diagnosis, prevention or mitigation of a disease are regulated by FDA via a risk-based paradigm.

• Risk-based regulation encompasses pre-market and post-market controls.
Questions?

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