FDA’s Regulation of Glaucoma Devices

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It is a Medical Device if it:

- Diagnoses, Cures, Mitigates, Treats or Prevents a Disease or Condition
- Affects the Function or Structure of the Body
- Does Not Achieve Intended Use Through Chemical Action
- Is Not Metabolized
Risk-Based Paradigm

The law gives us the flexibility to calibrate our regulatory approach to the level of potential risk posed by new products.

- Tonometers 510(k)
- Corneal Implants in Keratoconus HDE
- Intraocular Lenses PMA
Device Classifications

• CLASS I
  » Simple design, low risk
  » Most exempt from premarket submission

• CLASS II
  » More complex, higher risk
  » Premarket Notification [510(k)]

• CLASS III
  » Most complex, highest risk
  » Premarket Application [PMA]

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm
Class I: General Controls

- Establishment registration with the FDA
- Medical device listing with the FDA
- Quality systems regulation
- Labeling requirements
- Medical device reporting (MDR)
- Most Class I devices now exempt from Premarket notification [510(k)]
Class II: General Controls plus Special Controls

• General controls are insufficient to provide reasonable assurance of device’s safety and effectiveness

• Special Controls may include:
  » Performance standards (e.g., ANSI, ASA, ISO, ASTM)
  » FDA guidance documents
  » Device tracking
  » Patient registry

• Most require Premarket Notification [510(k)] to show substantial equivalence to a legally marketed “predicate” device
Class III: General Controls plus Premarket Approval

• Typically reserved for devices that:
  » Support/sustain human life, or
  » Have substantial importance in preventing health impairment, or
  » Potential unreasonable risk of illness or injury

• Requires Premarket Approval (PMA): reasonable assurance of safety and effectiveness

Required Regulatory Submissions

• Not exempt Class I or Class II -» 510 (k) (91% of Class 1 are exempt)

• Class III -» PMA
510(k)

• Section 510(k) of F.D. & C. Act

• Marketing clearance application

• Allows FDA to Determine Substantial Equivalence (SE) to a legally marketed device (predicate device) that is not subject to Premarket Approval (PMA)
A device is Substantially Equivalent (SE) if…

• In comparison to a legally marketed device (predicate), it
  » Has the same intended use, and
  » Has the same technological characteristics as the predicate device,

OR…
510(k) - Substantial Equivalence

- Has the same intended use, and

- Has different technological characteristics and the information in the 510(k):
  - Does not raise new types of questions of safety and effectiveness, and
  - Performance data demonstrates that it is as safe and effective as the predicate
Premarket Approval (PMA)

- An application requesting approval to market
- Class III Devices are subject to Premarket Approval
- Application needs to contain sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use
Safety and Effectiveness Determination

• Considerations
  » Intended population
  » Conditions of use for the device
  » Probable benefit to health vs. probable injury or illness from use
  » Reliability of the device

• Based only on Valid Scientific Evidence
Glaucoma Devices

- Diagnostic Tools – typically require 510(k)
- Therapeutic – can require 510(k) or PMA
Glaucoma Devices: Diagnostic Tools

- **Tonometers**
- **Fundus cameras**
- **Devices for functional tests**
  - Standard Automated Perimetry (SAP))
  - Short-Wavelength Automated Perimetry (SWAP)
  - Frequency Doubling Technology (FDT)
- **Devices for structural tests**
  - SLO polarimetry (GDx)
  - CSLO Topography (HRT)
  - Optical Coherence Tomography (OCT)
Therapeutic Glaucoma Devices¹

• Lasers (Nd:YAG, Argon, etc.) - 510(k)

• Implantable Glaucoma Devices – 510(k) or PMA
  » Refractory Population*
  » Non-Refractory Population*

*as defined in ANSI Z80.27

¹ no surgical tools (e.g., Trabectome) have been cleared for the treatment of glaucoma
Implantable Therapeutic Devices – Refractory Population

• Devices indicated for subjects who have failed medical treatments and filtering surgery and for subjects who are likely to fail filtering surgery

• All cleared glaucoma shunts have indications for IOP reduction

• All were cleared via 510(k) process
  » demonstration of substantial equivalence to a predicate (legally marketed shunt)
Implantable Therapeutic Devices – Non-Refractory Population

• Two devices currently approved:
  » Staar Aquaflow Collagen Glaucoma Drainage Device
  » Glaukos iStent

• Many devices under investigation
  » All require Premarket Approval Application (PMA) – demonstration of reasonable safety and effectiveness for proposed indications for use
Obtaining FDA Input
Early in the Development

Pre-Submission Program

• Facilitates device development / innovation by providing informal FDA feedback on proposed:
  » Preclinical testing
  » Clinical trial design (e.g., endpoints, inclusion/exclusion criteria, statistical analysis plan)

• Review goal: 75 days

• Provides an opportunity for a meeting with the FDA

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm
Thank you