FDA's Regulation of Glaucoma Devices

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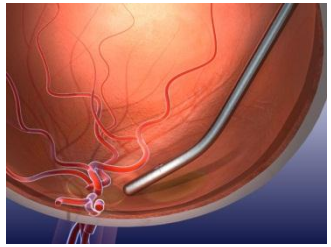
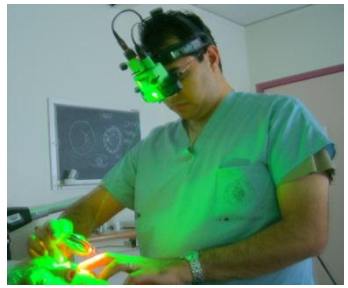
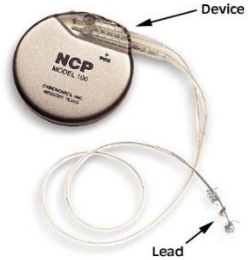
It is a Medical Device if it:

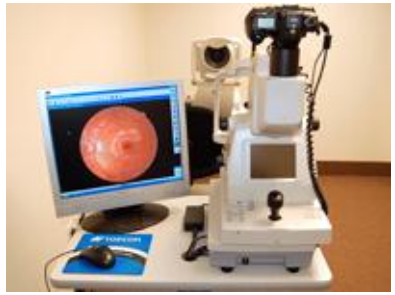
- Diagnoses, Cures, Mitigates, Treats or Prevents a Disease or Condition
- Affects the Function or Structure of the Body
- Does Not Achieve Intended Use Through Chemical Action
- Is Not Metabolized

The Diversity of Medical Devices





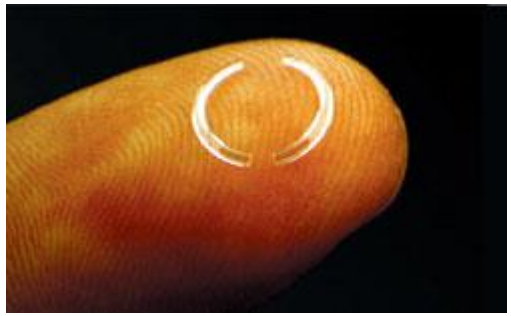




Risk-Based Paradigm

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

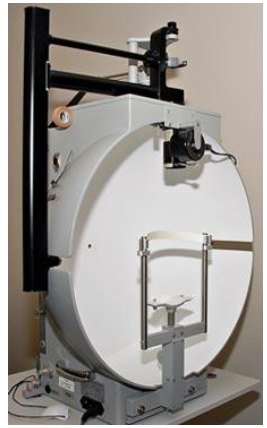
Device Classifications

- **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

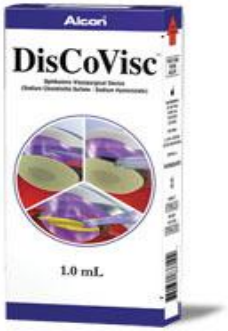
- Special Controls may include:
  - » Performance standards (e.g., ANSI, ASA, ISO, ASTM)
  - » FDA guidance documents
  - » Device tracking
  - » Patient registry

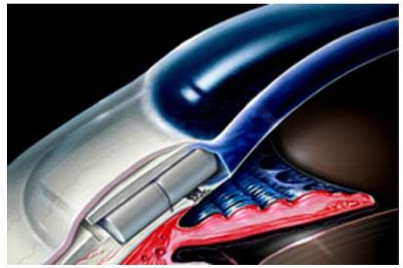
- Most require Premarket Notification [510(k)] to show substantial equivalence to a legally marketed "predicate" device

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





http://staar.com/html/glaucoma-products.html

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)

510(k) – Substantial Equivalence

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 Devices[1]

- 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