Current Regulatory Pathways for Glaucoma Imaging Devices

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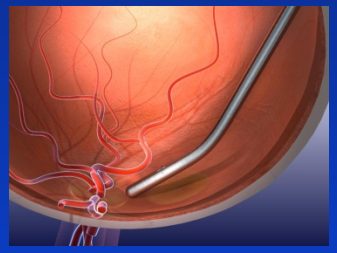
Financial Disclosure

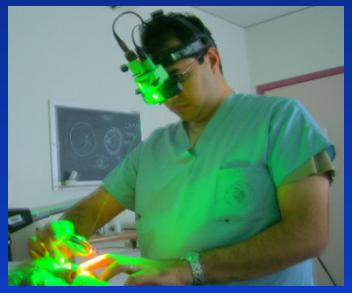
- I have no financial interests or relationships to disclose

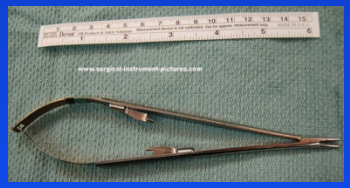
It is a Medical Device if it:

- 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



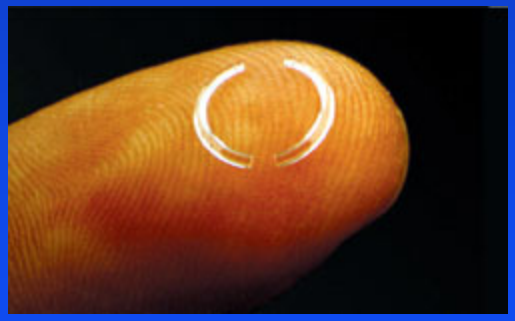




Risk-Based Paradigm

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
- Most Class I devices now exemp 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

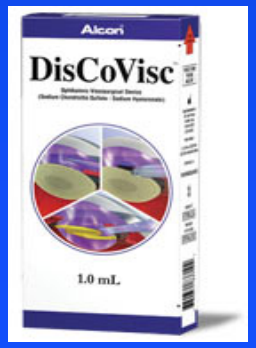
- Special Controls may include:
  - » Performance standards (e.g., ANSI, ASA, ISO, ASTM)
  - » FDA guidance documents
  - » Device tracking
  - » Patient registry

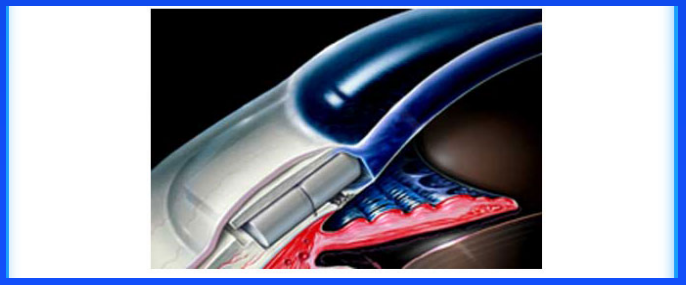
- Most require Premarket Notification [510(k)] to show substantial equivalence to a legally marketed "predicate" device

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

Ophthalmic Examples

CLASS I	CLASS II	CLASS III
VA charts	Tonometers	IOLs
Manual Surgical Instruments (cannulas, blades, forceps, etc.)	Imaging Devices (GDx, HRT, OCT)	Excimer lasers
Perimeters	Lasers (ALT, SLT)	Viscoelastics
	Implantable Glaucoma Devices (refractory indications)	Endotamponades
		Implantable Glaucoma Devices (non-refractory indications)

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

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 it:

- Has the same intended use, and
- Has the same technological characteristics as the predicate device, or:

A device is Substantially Equivalent (SE) if:

- Has the same intended use, and
- Has different technological characteristics and the information in the 510(k):
  - Does not raise new questions of safety and effectiveness, and
  - Demonstrates it is as safe and effective as the predicate

Premarket Approval (PMA)

- An application requesting clearance 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

Marketing Pathways

PMA

- Approval
- Class III
- Reasonable assurance of safety and effectiveness
- Contain valid scientific evidence

510(k)

- Clearance
- Class II
- Device is substantially equivalent to the predicate
- Comparison to legally marketed predicate device

Examples of Diagnostic Glaucoma Devices cleared via 510(k) process

- Slit Lamps
- Tonometers
- Fundus cameras
- SLO Polarimetry (GDx)
- CSLO Topography (HRT)
- Ultrasound Biometry
- Optical Coherence Tomography (OCT)

510(k) – Key Components

- Device Description
  - What is it? How does it work?
- Proposed Indications for Use Statement
  - Level of data requirements is IFU dependent
- Performance Data
  - Demonstration of substantial equivalence to the predicate
- Proposed Labeling

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

510(k) Labeling

- Includes user manuals, brochures, websites, package inserts, etc

- Describes diagnostic device performance and appropriate use of the device to mitigate risks
  - » Performance data should be included in labeling for consideration by the user
  - » Appropriate contraindications, warnings, and precautions in labeling

21 CFR 807.87

Obtain 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: 60 days
- Provides an opportunity for a meeting with the FDA

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

Summary Points

- The regulation of Glaucoma Diagnostic Devices is usually via the 510(k) path through a substantial equivalence comparison
- FDA reviews labeling to ensure that it provides a summary of the performance data to allow the user to understand the limitations of the device, and adequately interpret the device output
- 510(k) summary describes the information submitted to make FDA's determination of substantial equivalence

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm

Summary Points

- FDA clearance of a device as a diagnostic tool should not be misinterpreted to mean that the device can be a stand-alone diagnostic modality for specific diseases

- Clinicians should avoid:
  - Misinterpretation of results and possibility of improper diagnosis or over-treatment
  - Unsupported changes in practice due to over-reliance on diagnostic test results