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.
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 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

# Ophthalmic Examples

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<td>Imaging Devices (GDx, HRT, OCT)</td>
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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.