Intraocular Lens Regulation

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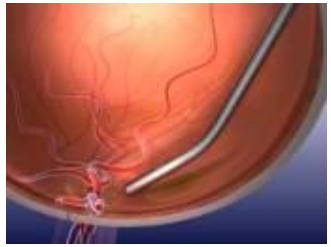
Disclosures

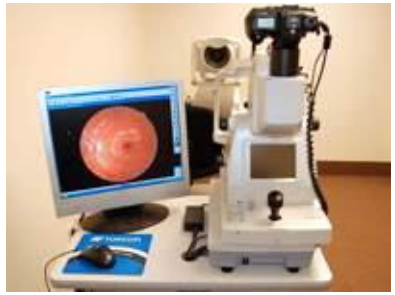
No Financial Relationships to Disclose

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

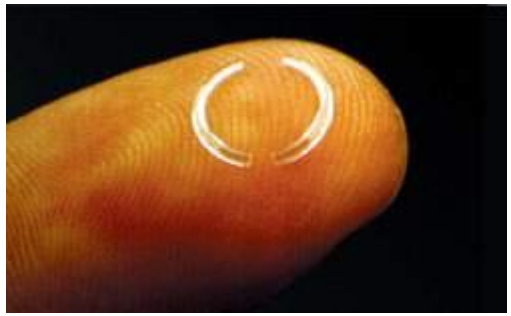




Risk-Based Paradigm

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 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

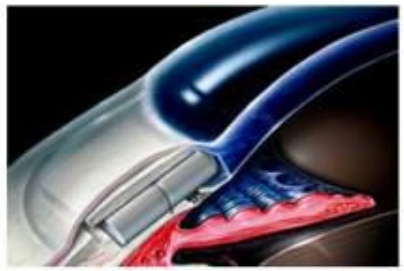
- Special Controls may include:
  - » Performance standards (e.g., ANSI, ASA, ISO, ASTM)
  - » FDA guidance documents
  - » Device tracking
  - » Patient registry

- 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

Intraocular Lenses

- All IOLs are Class 3 medical devices requiring premarket approval (PMA)
- 59 Original PMAs Approved
  - » Most PMAs have supplements with IOL modifications → hundreds of different lenses on the market
- Currently approved "premium" IOLs
  - » 3 multifocals
  - » 1 accommodating
  - » 4 toric
  - » 2 phakic
- Many in the pipeline
  - » Phakic, aspheric, multifocal, toric, accommodative and combinations of the above

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

Ophthalmic Standards

- **FDA working with the American National Standards Institute (ANSI) and the International Standards Organization (ISO) since the 1980's**
- **FDA Recognized Standards**
  - » **A consensus standard that FDA has evaluated and recognized for use in satisfying a regulatory requirement and for which FDA has published a notice in the Federal Register (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm)**
  - » **36 recognized ophthalmic standards**

Ophthalmic Standards

- **FDA recognized ANSI/ISO standards provide recommendations on the preclinical requirements and clinical study design (Monofocal, MIOL, PIOL)**

- **Incomplete group of recognized ANSI/ ISO Standards for other "Premium" IOLs**

Recognized IOL Standards

- **Preclinical requirements:**
  - » ISO 11979- 2, 3, 5, 6, 8
  - » ANSI Z80 – 7, 12, 13
- **Clinical recommendations (study design, endpts, SPE*, etc.):**
  - » Monofocal IOL (ANSI Z80.7, ISO 11979-7)
  - » Multifocal IOL (ANSI Z80.12, ISO 11979-9)
  - » Phakic IOL (ANSI Z80.13, ISO 11979-10)
- **ISO TR 22979**
  - » IOL modifications
  - » Defines “parent IOL”

* SPE (safety and performance endpoints): basic historical safety and effectiveness data (FDA Grid) incorporated in ISO 11979-7

ISO TR 22979

- **Level A modifications: No clinical investigation.**
  - » **All safety and performance questions can be adequately addressed by non-clinical testing.**
- **Level B modifications: Limited clinical investigation of 100 subjects followed up to and including Form 4, see ISO 11979-7.**
  - » **For modifications that raise safety and performance questions that can be adequately addressed with a limited clinical investigation.**
- **Level C modifications: Full clinical investigation as defined in ISO 11979-7.**
  - » **For modifications that raise safety and performance questions that can only be addressed by a full clinical investigation.**

IOL Standards

- Clinical Investigation guidance provided in Consensus Standards
- Study Design:
  - Sample size (statistical considerations)
  - Study duration
  - Inclusion/exclusion criteria
- Clinical Evaluation
  - Examination Schedule
  - Clinical Tests
  - Test Methodologies
- Safety and Effectiveness Analyses

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