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.
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

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/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