Ophthalmic Medical Devices and Risk Communications Joint Panel Meeting: FDA Presentations

1. Regulation and Pre-Market Review of Contact Lens Care Products, **Dr. J. Angelo Green**
2. Hydrogen Peroxide Contact Lens Care Product History and Use, **Dr. Bernard P. Lepri**
3. Hydrogen Peroxide Contact Lens Care Product Medical Device Reports (MDR), **Mr. Constantino Castillo**
4. FDA Patient Preference Initiative, **Ms. Katie O'Callaghan**

Regulation and Pre-Market Review of Contact Lens Care Products

J. Angelo Green, Ph.D., DABT
Acting Branch Chief
Contact Lens and Retinal Devices Branch
Division of Ophthalmic and Ear, Nose and Throat Devices
Center for Devices and Radiological Health
Food and Drug Administration

Definition of a Medical Device[1]

- Intended to diagnose, cure, mitigate, treat or prevent a disease/condition, or
- Intended to affect the structure or function of the body, and
- Does not achieve intended use through chemical action or metabolism

[1]Sec. 201, Food, Drug and Cosmetic Act

CL Care Products

- A contact lens care product is an accessory device intended for use in the cleaning, rinsing, disinfecting/conditioning, lubricating/ rewetting, or storing of a contact lens[1]

[1]21 CFR 886.5928 and 21 CFR 886.5918

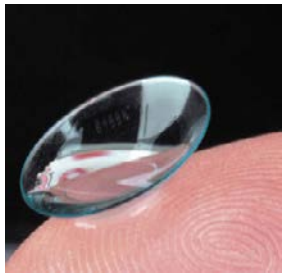
Types of CL Care Products

- Saline – preserved, non-preserved
- Daily, weekly cleaners and protein removers
- Multipurpose solutions (clean/rinse/disinfect/store)
- Lubricants/rewetting drops
- Hydrogen peroxide solutions

Risk-Based Paradigm[1]

The law gives us the flexibility to calibrate our regulatory approach to the level of potential risk posed by new products

Sunglasses



Daily Wear Contact Lenses

Intraocular Lenses

Class I	Class II	Class III
Low risk	Moderate risk	Highest risk
Most exempt from premarket submission	Premarket notification [510(k)]	Premarket Approval Application (PMA)
General controls	General controls and special controls	General controls

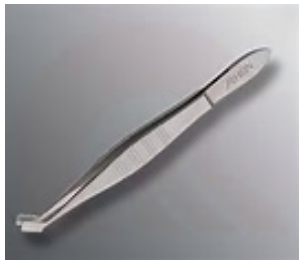
[1]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/

Regulatory History of Contact Lenses and Care Products

- Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) of 1976,
  - » legal authority to regulate contact lenses and care products, were categorized as class III medical devices
- Safe Medical Devices Act of 1990,
  - » all contact lens care products were reclassified in 1997 to class II
  - » As a result of reclassification, FDA issues a special control guidance document; considered necessary to regulate these products as class II

General Controls[1]

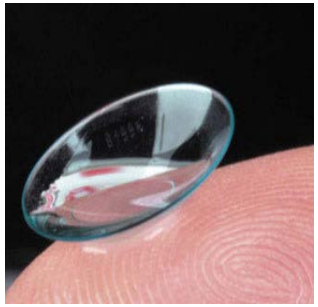
- Prohibition of adulterated or misbranded devices
- Good Manufacturing Practices (GMPs)
- Registration of manufacturing facilities
- Listing of device types
- Records and reports
- Repair, replacement, refund



[1]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm

Special Controls[1]

- Performance standards (e.g., ANSI[2], ISO[3], ASTM[4])
- Guidance documents
- Device tracking
- Premarket data requirements
- Postmarket surveillance
- Special labeling requirements



[1]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm
[2]ANSI: American National Standards Institute, [3]ISO: International Organization for Standardization
[4]ASTM: American Society for Testing and Materials

510(k) – Premarket Notification

- Section 510(k) of F.D. & C. Act
- Moderate risk devices (Class II devices)
- Most 510(k) submissions include performance data (bench, animal, and/or clinical)
- Decision is typically rendered in 90 days
- Allows FDA to Determine Substantial Equivalence (SE) to a predicate (U.S. legally marketed) device

CL Premarket Submissions

- Materials/Chemistry
- Manufacturing
- Sterility
- Shelf Life
- Biocompatibility
- Labeling
- Performance testing: nonclinical
- Performance testing: clinical

General Recommendations in FDA Guidance Documents

FDA Guidance Document[1]

- Describes FDA's interpretation of, or policy on, a regulatory issue
  - » Device-specific
  - » Labeling
  - » Manufacturing
  - » Clinical studies
    - – Sample size
    - – Study Design
    - – Data Analysis

[1]www.fda.gov/cdrh/guidance.html

Contact Lens Care Product Guidance

- 1997 Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products[1]
- 2010 Guidance for Industry and Food and Drug Administration Staff - Contact Lens Care Products Labeling[2]

Ophthalmic Medical Devices and Risk Communications Joint Panel Meeting: FDA Presentations

1. Regulation and Pre-Market Review of Contact Lens Care Products, **Dr. J. Angelo Green**
2. Hydrogen Peroxide Contact Lens Care Product History and Use, **Dr. Bernard P. Lepri**
3. Hydrogen Peroxide Contact Lens Care Product Medical Device Reports (MDR), **Mr. Constantino Castillo**
4. FDA Patient Preference Initiative, **Ms. Katie O'Callaghan**