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

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Division of Ophthalmic and Ear, Nose and Throat Devices
Center for Devices and Radiological Health
Food and Drug Administration
Definition of a Medical Device

• 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

1Sec. 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

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

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<td>Low risk</td>
<td>Moderate risk</td>
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<td>Most exempt from premarket submission</td>
<td>Premarket notification [510(k)]</td>
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<td>General controls</td>
<td>General controls and special controls</td>
<td>General controls</td>
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1http://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

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

1http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm
Special Controls\textsuperscript{1}

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

\textsuperscript{1}http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm
\textsuperscript{2}ANSI: American National Standards Institute, \textsuperscript{3}ISO: International Organization for Standardization
\textsuperscript{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

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

1www.fda.gov/cdrh/guidance.html
Contact Lens Care Product Guidance

• 1997 Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products¹

• 2010 Guidance for Industry and Food and Drug Administration Staff - Contact Lens Care Products Labeling²
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