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Acknowledgements

- Dr. Angelo Green
- Dr. Marc Robboy
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Medical Device ¹

- Definition
 - 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
- There are no generic medical devices



Device Classification ¹

- **CLASS I**
 - Simple design, low risk
 - General Controls
 - Most exempt from premarket submission
- **CLASS II**
 - More complex, moderate risk
 - General Controls plus Special Controls
 - Premarket Notification [510(k)]
 - » Demonstration of substantial equivalence
- **CLASS III**
 - Most complex, highest risk
 - General Controls and Premarket Approval (PMA)
 - » Reasonable assurance of safety and effectiveness



Contact Lenses (CLs)

- FDA regulates all contact lenses (CLs)
- Classification
 - Class II: Daily wear lenses (soft and rigid gas permeable)
 - Class III: Extended wear lenses (soft and rigid gas permeable)
 - » available for overnight or continuous wear ranging from one to six nights or up to 30 days
- CL indications
 - to correct refractive error



Demographics of Contact Lens Use

- 35% wear daily disposable contact lenses
- 66.6% are female²
- Over 90% of adult CL wearers use soft contact lenses¹
- 3.6 million wearers between 12 to 17 years¹
- 7.5 million wearers between 18 to 24 years¹

¹ <https://www.cdc.gov/mmwr/volumes/66/wr/mm6632a2.htm>

²



Risks from Use of Contact Lenses

- Microbial keratitis
- Allergies affecting the eyes
- Giant Papillary Conjunctivitis (GPC)
- Corneal abrasion
- Contact Lens-induced Acute Red Eye (CLARE)
- Corneal infiltrates
- Dry eyes
- Neovascularization

<https://www.cdc.gov/contactlenses/otherecomplications.html>



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FDA Safeguards

- Review of premarket submissions
- Standards
- Guidance
- Postmarket surveillance
 - MedWatch, PAS, and 522 studies
- Research
- Outreach



CL Premarket Submissions

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

General recommendations describe in FDA Guidance and FDA-recognized consensus standards



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Chemistry Review of Contact Lenses

- Pr y-9.4 (L)083 ()1.66(C)868(tf)2651 (ec)0.69(tt p1.7

Clinical Assessment of CL Performance^{1,2}



- Clinical evidence supports marketing clearance/approval for





Contact Lens Labeling (contd)

- Base Curve (BC)
 - Affects the alignment of the lens to the topography of the central cornea
 - Same BC for different brands may not be clinically equivalent
- Diameter
 - Affects lens centration
 - Same diameter for different brands may not be clinically equivalent
- Dioptric Power
 - Affects strength of correction
 - Improper power may result in reduced visual acuity, eye strain and headaches



- There is currently no regulatory pathway for marketing of generic CLs
- The current clinical care paradigm does not support substitution of CLs brands without a clinical evaluation
- Additional research and education is needed regarding



FDA Guidance¹

- Describes FDA's interpretation of, or policy on, a regulatory issue
 - Productspecific
 - Labeling
 - Manufacturing
 - Clinical studies
 - » Sample Size
 - » Study Design
 - » Data Analysis
- FDA Contact Lens Guidance outlines recommended testing for manufacturers²

¹www.fda.gov/cdrh/guidance.html

²<http://www.fda.gov/RegulatoryInformation/Guidances/ucm080928.htm>



Postmarket

- To report adverse events including contact lens related infections
 - FDAMedwatch
<https://www.fda.gov/Safety/MedWatch/default.htm>
- To report unlawful internet sales or contact lens vendors selling without a prescription
 - FDA Website: Report a Problem
<https://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>
- 522 study: FDA mandated post market surveillance study
 - List of studies and study status available to the public
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cf>

FDA Research



- FDA conducted research to:
 - Categorize the numerous silicone hydrogel lenses to address concerns with dimensional stability and toxicity
 - Evaluate the efficacy of care product solutions in the presence of lenses - real world testing
 - Develop Acanthamoeba test method

- Outcomes of research published in Eye and Contact Lens:
 - [Material Properties That Predict Preservative Uptake for Silicone Hydrogel Contact Lenses.](#)
Green JA, Phillips KS, Hitchins VM, Lucas AD, Hoff ME, Hutter JC, Rorer EM, Eydelman MB.
 - [Impact of Contact Lens Materials on Multipurpose Contact Lens Solution Disinfection Activity Against *Serratia*](#)
Clavet CR, Chaput MP, Silverman MD, Striplin M, Shoff ME, Lucas AD, Hitchins VM, Eydelman MB.
 - [The Effects of Contact Lens Materials on a Multipurpose Contact Lens Solution Disinfection Activity Against *Staphylococcus aureus*.](#)
Shoff ME, Lucas AD, Brown JN, Hitchins VM, Eydelman MB.
 - [Strategies to Optimize Conditions for Testing Multipurpose Contact Lens Solution Efficacy Against *Acanthamoeba*.](#)
Shoff M, Eydelman MB.
 - [Proposed Silicone Hydrogel Contact Lens Grouping System for Lens Care Product Compatibility Testing.](#)
Hutter JC, Green JA, Eydelman MB.
 - [Preclinical Research to Aid in the Development of Test Methods for Contact Lenses and Their Care Products.](#)
Eydelman MB, Kiang T, Tarver ME, Alexander KY, Hutter JC.
 - [The Food and Drug Administration's Role in Establishing and Maintaining Safeguards for Contact Lenses and Contact Lens Care Products.](#)
Eydelman MB, Tarver ME, Kiang T, Alexander KY, Hutter JC.
 - [Optimized Protocol for Testing Multipurpose Contact Lens Solution Efficacy Against *Acanthamoeba*.](#)
Fedorko DP, Brocius JM, Adams KD, Hitchins VM, Hampton DL, Eydelman MB



Outreach: Websites & Consumer Updates



- Consumer-focused articles distributed to over 75,000 subscribers
 - “Decorative Contact Lenses: Is Your Vision Worth It?”
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm275069.htm>
 - “Improper Use of Decorative Contact Lenses May Haunt You”
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048902.htm>
 - “FDA Teams Up for Novel Campaign on Risks of Decorative Contact Lenses”
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm117117.htm>



Outreach: Medscape Commentaries & Interviews

- “Telling the FDA: Why Contact Lens Adverse Events Matter”

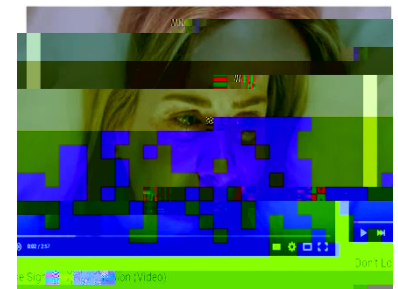
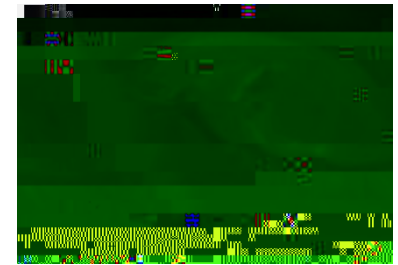
http://www.medscape.com/viewarticle/774062_3

- “Decorative Contact Lenses: Truly Frightening”

<http://www.medscape.com/viewarticle/773106>

Outreach: Videos

- **FDA Video**
 - “Improper Use of Decorative Contact Lenses May Haunt You”
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm187691.htm>
- **Public Service Videos**





Outreach: Social Media

- FDA launched a Twitter campaign regarding decorative CLs in 2012
 - Twilight Conferences (nationwide), ConCon, Hunger Games movie release, Chicago Comic & Entertainment Expo, Anime Boston
 - Sample message:
 - » Want to look like your favorite vampire? See an eye doctor before buying costume/fashion lenses. Link to flyer @twi_tour, #twilight
- FDA participated in CDC's Contact Lens Health Week Twitter Chat in 2015, 2016, and 2017
- FDA launched a Google AdWords Campaign in August 2015 during the CDC / FDA Twitter Chat

Questions?

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