Soft (Hydrophilic) Daily Wear Contact Lenses – Performance Criteria for Safety and Performance Based Pathway

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Draft Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the DHT1A: Division of Ophthalmic Devices at 301-796-5620 or Angelo Green at Angelo.Green@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides performance criteria for soft (hydrophilic) daily wear contact lenses in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for soft (hydrophilic) contact lenses will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope/Device Description

The soft (hydrophilic) daily wear contact lenses that are the subject of this guidance are Class II devices and are regulated under 21 CFR 886.5925, with the product code LPL.

Intended Use/Indications for Use:
The soft (hydrophilic) daily wear contact lenses that fall within the scope of this guidance are prescription devices intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye for the optical correction of ametropia (myopia or hyperopia with or without astigmatism). The lenses are designed to be frequent replacement or daily disposable lenses.

Soft (hydrophilic) contact lenses with the following indications for use are <u>not</u> eligible for the Safety and Performance Based Pathway via this guidance:

- To correct presbyopia
- To enhance or alter the apparent color of the eye
- To act as a bandage or therapeutic lens
- For the management of keratoconus or irregular corneal conditions
- Lenses with special optical performance beyond that of correcting ametropia (e.g., blue light filtering)
- Lenses with special physical performance (retains moisture, lubricates, reduces deposits)
- Lenses with special health performance characteristics (e.g., relieves dry eye)

Device Design Characteristics:
The soft (hydrophilic) daily wear contact lenses that fall within the scope of this guidance are spherical or toric lenses made from polymacon, etafilcon A or hioxifilcon D polymeric materials as defined by the United States Adopted Name (USAN) Council and include the associated primary packaging components. Listed color additives are allowed for handling and visibility tinting only. The lenses are designed to be frequent replacement or daily disposable lenses.

Please note that this guidance document's scope does not include soft contact lens materials not specified in the scope of this document or rigid gas permeable contact lenses (21 CFR 886.5918).

Soft (hydrophilic) daily wear contact lenses with the following features are <u>not</u> eligible for the Safety and Performance Based Pathway via this guidance:

- Lenses made of materials not defined above
- Lens materials made of non-polymeric components

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- Lens materials with non-listed color additives
- Lenses with UV- additives not previously used in polymacon, etafilcon A or hioxifilcon D materials
- Lenses with coatings, whether directly or indirectly applied (e.g., wetting agents applied by immersion in packaging solution)
- Lens materials with special optical filtering capabilities (e.g., blue light filtering)
- Combination products

General guidance that is beyond the scope of this safety and performance guidance document regarding submission of a 510(k) for soft (hydrophilic) daily wear contact lenses (e.g., labeling), can be found in other FDA guidance documents.

FDA may determine, on a case-by-case basis, that additional data are necessary to evaluate whether the device is appropriate for the Safety and Performance Based Pathway. In situations where you determine that additional testing outside of those identified in this guidance are necessary to determine whether the device is appropriate for the Safety and Performance Based Pathway, we would encourage sponsors to submit a Pre-Submission[4] to engage in discussion with FDA prior to submission of the 510(k).

III. Testing Performance Criteria

If your device qualifies for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need to provide direct comparison testing against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g. Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the submission information sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance, Safety and Performance Based Pathway.[5] For additional information regarding the submission of non-clinical bench testing information, please refer to FDA's guidance: Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[6]

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Physicochemical and Optical Properties

1. **Test name:** Spectral Transmittance (%)
   Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
   - ISO 18369-3 *Ophthalmic optics - Contact lenses - Part 3: Measurement methods*
   - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

   Performance Criteria (polymacon): 93% ± 5%
   Performance Criteria (etafilcon A): 94% ± 5%
   Performance Criteria (hioxifilcon D): 96% ± 5%
   Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent, and ISO 18369-2:2017 *Ophthalmic optics - Contact lenses - Part 2: Tolerances* and ANSI Z80.20-2016 for tolerances.
   Submission Information: Results summary and Declaration of Conformity (DoC)

2. **Test name:** Ultra Violet (UV) Transmittance (%)
   Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
   - ISO 18369-3 *Ophthalmic optics - Contact lenses - Part 3: Measurement methods*
   - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

   Performance Criteria (polymacon): $\tau_{UVB} < 0.05\ \tau_V$; $\tau_{UVA} < 0.50\ \tau_V$
   Performance Criteria (etafilcon A): $\tau_{UVB} < 0.05\ \tau_V$; $\tau_{UVA} < 0.50\ \tau_V$
   Performance Criteria (hioxifilcon D): $\tau_{UVB} < 0.05\ \tau_V$; $\tau_{UVA} < 0.50\ \tau_V$
   τ_V = luminous transmittance of the contact lens, τ_{UVB} and τ_{UVA} are the average ultraviolet radiation transmittances of the contact lens, summated over the UVB (280 nm to 315 nm) and the UVA (316 nm to 380 nm) wavelengths respectively
   Performance Criteria Source: ANSI Z80.20-2016
   Additional Considerations: Only needed for materials with added UV absorbers
   Submission Information: DoC and Results Summary if using ISO 18369-3 for methodology, otherwise DoC if using ANSI Z80.20 for the methodology

3. **Test name:** Refractive Index
   Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
   - ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials*
   - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

   Performance Criteria (polymacon): 1.437 ± 0.005

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Performance Criteria (etafilcon A): 1.402 ± 0.005
Performance Criteria (hioxifilcon D): 1.407 ± 0.005
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent, and ISO 18369-2:2017 *Ophthalmic optics - Contact lenses - Part 2: Tolerances for tolerances*.
Submission Information: Results summary and DoC

4. **Test name:** Water Content (%)
Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
    - ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials*
    - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

Performance Criteria (polymacon): 38 ± 2%
Performance Criteria (etafilcon A): 58 ± 2%
Performance Criteria (hioxifilcon D): 54 ± 2%
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent and ISO 18369-2:2017 *Ophthalmic optics - Contact lenses - Part 2: Tolerances* for tolerances.
Submission Information: Results summary and DoC

5. **Test name:** Specific Gravity
Methodology: Any standard methodology accepted
Performance Criteria (polymacon): 1.124 ± 0.037
Performance Criteria (etafilcon A): 1.062 ± 0.041
Performance Criteria (hioxifilcon D): 1.214 ± 0.094
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent
Submission Information: Complete test report

6. **Test name:** Oxygen Permeability (Dk or [cm^2/s][ml O_2/ml x mmHg])
Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
    - ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials*
    - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

Performance Criteria (polymacon): 10.76×10^{-11} ± 20%
Performance Criteria (etafilcon A): 22.43×10^{-11} ± 20%
Performance Criteria (hioxifilcon D): 20.84×10^{-11} ± 20%

Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent and ISO 18369-2:2017 *Ophthalmic optics - Contact lenses - Part 2: Tolerances for tolerances*.
Submission Information: Results summary and DoC

7. **Test name:** Extractables (< 1% with water and hexane)
Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
    - ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials*
    - ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

Performance Criteria (polymacon): <1% extractables, hexane and water
Performance Criteria (etafilcon A): <1% extractables, hexane and water
Performance Criteria (hioxifilcon D): <1% extractables, hexane and water
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent.
Submission Information: Results summary and DoC

Mechanical Properties

8. **Test name:** Modulus (MPa or N/mm^2)
Methodology: One of the following FDA currently-recognized consensus standards (as applicable):
    - ASTM D882 *Standard Test Methods for Tensile Properties of Thin Plastic Sheeting*
    - ANSI Z80.20 - *American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

Performance Criteria (polymacon): 0.62 ± 0.25 MPa
Performance Criteria (etafilcon A): 0.42 ± 0.09 MPa
Performance Criteria (hioxifilcon D): 0.36 ± 0.10 MPa
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent.
Submission Information: Results summary and DoC

9. **Test name:** Tensile Strength (MPa or N/mm^2)
Methodology: ASTM D882 *Standard Test Methods for Tensile Properties of Thin Plastic Sheeting*
Performance Criteria (polymacon): 0.63 ± 0.11 MPa
Performance Criteria (etafilcon A): range of 0.07 to 0.41 MPa
Performance Criteria (hioxifilcon D): 0.65 ± 0.26 MPa
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent.

Submission Information: Results summary and DoC

10. **Test name:** Elongation at Break (%)
Methodology: ASTM D882 *Standard Test Methods for Tensile Properties of Thin Plastic Sheeting*
Performance Criteria (polymacon): 240 ± 108%
Performance Criteria (etafilcon A): range of 50 to 340%
Performance Criteria (hioxifilcon D): 249 ± 69%
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions previously found to be substantially equivalent.
Submission Information: Results summary and DoC.

Packaging Solution

11. **Test name:** Packaging Solution pH
Methodology: Any standard methodology accepted
Performance Criteria (all materials): 7.2 – 7.4
Performance Criteria Source: Aggregated cleared 510(k) submissions
Submission Information: Results summary

12. **Test name:** Packaging Solution Osmolality (osmol/kg)
Methodology: Any standard methodology accepted
Performance Criteria (all materials): 280-320 osmol/kg
Performance Criteria Source: Aggregated cleared 510(k) submissions
Submission Information: Results summary

Sterilization

13. **Test name:** Sterilization (devices labeled as sterile)
Methodology: FDA currently-recognized version of the following consensus standards (as applicable):
    - ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
    - ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

Performance Criteria: Validation testing should demonstrate the cleanliness and sterility of the device to a sterility assurance level of 10^{-6}. You should provide a description of the packaging (sterile barrier system) and how it will maintain device sterility, and a description of the package test methods per ISO 11607-2 and package test data.
Performance Criteria Source: FDA's guidance:

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- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[7]

Additional Considerations: Please note that for devices considered in this guidance these recommendations pertain solely to moist heat sterilization. Any other sterilization method (e.g., ethylene oxide, radiation, or dry heat) is outside the scope of this guidance.
Submission Information: If using an Established Category A sterilization method, you should provide the information described in Section V.A. of the FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile"; the validation data itself is not needed to demonstrate substantial equivalence.

Biocompatibility

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[8] referred to in the rest of this document as the CDRH Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as "Surface Devices" with a "limited" mucosal membrane contact duration of ≤ 24 hours and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Ocular Irritation

Rationale in Lieu of Testing: If the subject device is manufactured from the identical blank polymer buttons and identical packaging materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in device design are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility.

Testing: If you determined that testing is needed to address some or all of the identified endpoints, FDA recommends that complete test reports for both the lens and packaging materials be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the CDRH Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below resulting in the need for submission of a Traditional, Special, or Abbreviated 510(k).

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

14. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
Methodology: FDA currently-recognized versions of biocompatibility consensus standards
Performance Criteria: All direct or indirect tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
Performance Criteria Source: The CDRH Biocompatibility Guidance
Additional Considerations: For any biocompatibility test samples with an adverse biological response, you should explain in your biocompatibility evaluation why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the CDRH Biocompatibility Guidance. For standard biocompatibility methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
Submission Information: Refer to CDRH Biocompatibility Guidance

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