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

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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.

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

Preface

Public Comment

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

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 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 (you) 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 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 consensus 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 entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[3]

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic

[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.

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. Background

In September 2019, FDA issued a guidance to describe an optional pathway – the Safety and Performance Based Pathway[4] – for certain, well understood device types, where a submitter could demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device. In order to identify the specific set of performance criteria appropriate to satisfy a submitter's comparison to an appropriate predicate for a given device-type, FDA has determined that the performance criteria represent performance that meets the performance of one or more existing, legally marketed devices of that device type. Specifically, FDA relied on the experience and expertise of FDA staff, information in literature, and analyses of data available to FDA on legally marketed soft (hydrophilic) daily wear contact lenses to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for soft (hydrophilic) daily wear contact lenses as described in this guidance. FDA recognizes that in some cases, it may be more burdensome for a submitter to conduct testing against an appropriate predicate device to demonstrate equivalence for the necessary set of performance and technological characteristics than to demonstrate their device meets appropriate performance criteria established by FDA. Accordingly, we concluded that the optional device-specific Safety and Performance Based Pathway utilizing the performance criteria identified in this guidance provides a less burdensome policy consistent with the public health.

III. 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 and/or characteristics are outside the scope of this guidance:

- To correct presbyopia
- To enhance or alter the apparent color of the eye
- To act as a bandage or therapeutic lens

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

- 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 (e.g., 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. Polymacon, etafilcon A, and hioxilfilcon D represent well-established contact lens materials that have been used in many 510(k)s by numerous contact lens manufacturers. Listed color additives[5] are used for handling and visibility tinting only. The lenses are designed to be frequent replacement or daily disposable lenses.

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

In addition, soft (hydrophilic) daily wear contact lenses with the following features are outside the scope of this guidance:

- Lenses made of materials not defined above
- Lens materials made of non-polymeric components
- 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)
- Lenses with novel packaging solution ingredients not used in any previously marketed contact lens packaging solution or care product
- Lens materials with special optical filtering capabilities (e.g., blue light filtering)
- Lenses with new spherical or toric optical designs that have not previously been marketed
- Combination products

Some of the recommendations in this safety and performance guidance may assist in complying with some of the special controls for soft daily wear contact lenses. For information regarding the special controls for soft daily wear contact lenses, see "Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses."[6] Descriptive information such as that related to the device description, United States Adopted Name Council (USAN) designation, finished lens parameters and tolerances and general manufacturing information should be

[5] See 21 CFR Part 73 Subpart D.
[6] Available at https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-daily-wear-contact-lenses-premarket-notification-510k-guidance-document.

provided as recommended in the above guidance. Similarly, general information that is beyond the scope of this safety and performance guidance document regarding submission of a 510(k) for daily wear contact lenses (i.e., labeling and shelf life), can also be found in the above guidance.

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 you to submit a Pre-Submission[7] to engage in discussion with FDA prior to submission of the 510(k).

IV. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, we do not expect you 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)) recommended below for each test or evaluation. Consistent with FDA policy for all 510(k) submissions, for all 510(k) submissions under the Safety and Performance Based Pathway, FDA may request and review underlying data demonstrating that a new device meets the FDA-identified performance criteria and testing methodology, as necessary. Unless otherwise identified in the performance criteria sections below, test information such as summary results or test protocols should be submitted as part of the 510(k) as described in FDA's guidance, Safety and Performance Based Pathway.[8] 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.[9]

FDA believes that the testing and performance criteria identified in this section provide at least the same level of protection of the public health and safety as the testing described in the guidance document entitled, "Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses."[10] To the extent the recommendations in this section depart from

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.
[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.
[10] Note that tests involving leachability, lens solution compatibility, and preservative uptake and release identified in the guidance document, "Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses," are mainly driven by material characteristics and properties of soft daily wear contact lenses that have been defined and incorporated into the testing performance criteria identified in this section.

previously issued recommendations in the above guidance document, this section supersedes those previous recommendations.

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*
   - We recommend measurement of the spectral transmittance with the thickest version of the lens to be marketed

   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*
   - We recommend measurement of the UV transmittance with the thinnest version of the UV lens to be marketed

   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):

- ISO 18369-4 *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
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):
   - ISO 18369-4 *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):
   - ISO 18369-4 *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 x 10^{-11} ± 20%
Performance Criteria (etafilcon A): 22.43 x 10^{-11} ± 20%
Performance Criteria (hioxifilcon D): 20.84 x 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):
    - ISO 18369-4 *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

<u>Mechanical Properties</u>

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 as described in ISO 11607-2 and package test data.
Performance Criteria Source: FDA's guidance:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[11]

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"; generally, 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 the FDA guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[12] referred to in the rest of this document as the FDA 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, as referenced in Attachment A of the CDRH Biocompatibility Guidance, with the following FDA currently-recognized consensus standards.

- Cytotoxicity - ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- Sensitization - ISO 10993-10 *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- Ocular Irritation - ISO 10993-10 *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*; ISO 10993-23 *Biological evaluation of medical devices – Part 23: Tests for 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, as described in Attachment E of the FDA Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified;

[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.
[12] 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.

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).

14. **Test name:** Biocompatibility endpoints (identified from FDA 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 FDA Biocompatibility Guidance
Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain 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 FDA 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 FDA Biocompatibility Guidance