

1 **Soft (Hydrophilic) Daily Wear Contact**
2 **Lenses – Performance Criteria for**
3 **Safety and Performance Based**
4 **Pathway**

7 **Draft Guidance for Industry and**
8 **Food and Drug Administration Staff**

11 ***DRAFT GUIDANCE***

13 **This draft guidance document is being distributed for comment purposes**
14 **only.**

16 **Document issued on March 4, 2020.**

19 You should submit comments and suggestions regarding this draft document within 60 days of
20 publication in the *Federal Register* of the notice announcing the availability of the draft
21 guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written
22 comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630
23 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number
24 listed in the notice of availability that publishes in the *Federal Register*.

26 For questions about this document, contact the DHT1A: Division of Ophthalmic Devices at 301-
27 796-5620 or Angelo Green at Angelo.Green@fda.hhs.gov.



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

Preface

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DRAFT

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

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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This draft guidance provides performance criteria for soft (hydrophilic) daily wear contact lenses in support of the [Safety and Performance Based Pathway](#).¹ Under this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Pathway for soft (hydrophilic) contact lenses will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.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>

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78 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
79 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
80 be viewed only as recommendations, unless specific regulatory or statutory requirements are
81 cited. The use of the word *should* in Agency guidance means that something is suggested or
82 recommended, but not required.
83

84 **II. Scope/Device Description**

85 The soft (hydrophilic) daily wear contact lenses that are the subject of this guidance are Class II
86 devices and are regulated under 21 CFR 886.5925, with the product code LPL.
87

88 **Intended Use/Indications for Use:**

89 The soft (hydrophilic) daily wear contact lenses that fall within the scope of this guidance are
90 prescription devices intended to be worn directly against the cornea and adjacent limbal and
91 scleral areas of the eye for the optical correction of ametropia (myopia or hyperopia with or
92 without astigmatism). The lenses are designed to be frequent replacement or daily disposable
93 lenses.
94

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

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

106 **Device Design Characteristics:**

107 The soft (hydrophilic) daily wear contact lenses that fall within the scope of this guidance are
108 spherical or toric lenses made from polymacon, etafilcon A or hioxifilcon D polymeric
109 materials as defined by the United States Adopted Name (USAN) Council and include the
110 associated primary packaging components. Listed color additives are allowed for handling and
111 visibility tinting only. The lenses are designed to be frequent replacement or daily disposable
112 lenses.
113

114 Please note that this guidance document's scope does not include soft contact lens materials not
115 specified in the scope of this document or rigid gas permeable contact lenses (21 CFR 886.5918).
116

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

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

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

128
129 General guidance that is beyond the scope of this safety and performance guidance document
130 regarding submission of a 510(k) for soft (hydrophilic) daily wear contact lenses (e.g., labeling),
131 can be found in other FDA guidance documents.

132
133 FDA may determine, on a case-by-case basis, that additional data are necessary to evaluate
134 whether the device is appropriate for the Safety and Performance Based Pathway. In situations
135 where you determine that additional testing outside of those identified in this guidance are
136 necessary to determine whether the device is appropriate for the Safety and Performance Based
137 Pathway, we would encourage sponsors to submit a Pre-Submission⁴ to engage in discussion
138 with FDA prior to submission of the 510(k).

139

140 **III. Testing Performance Criteria**

141 If your device qualifies for submission through the Safety and Performance Based Pathway, and
142 you choose to use that option, you do not need to provide direct comparison testing against a
143 legally marketed predicate device to demonstrate substantially equivalent performance
144 characteristics. To ensure that the performance criteria outlined in this guidance remain
145 contemporary and take into account relevant data from recent clearances, FDA recommends that
146 you provide a results summary for all tests evaluated in addition to the other submission
147 information (e.g. Declaration of Conformity (DoC)) identified for each test or evaluation below.
148 Unless otherwise identified in the submission information sections below, test information such
149 as results summary, test protocols, or complete test reports should be submitted as part of the
150 510(k) as described in FDA’s guidance, [Safety and Performance Based Pathway](#).⁵ For additional
151 information regarding the submission of non-clinical bench testing information, please refer to
152 FDA’s guidance: [Recommended Content and Format of Non-Clinical Bench Performance
153 Testing Information in Premarket Submissions](#).⁶

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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>

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156 Physicochemical and Optical Properties

157

158 1. **Test name:** Spectral Transmittance (%)

159 **Methodology:** One of the following FDA currently-recognized consensus standards (as
160 applicable):

- 161 • ISO 18369-3 *Ophthalmic optics - Contact lenses - Part 3: Measurement methods*
- 162 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
163 *Standard Terminology, Tolerances, Measurements and Physicochemical*
164 *Properties*

165 **Performance Criteria (polymacon):** 93% ± 5%

166 **Performance Criteria (etafilcon A):** 94% ± 5%

167 **Performance Criteria (hioxifilcon D):** 96% ± 5%

168 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
169 510(k) submissions previously found to be substantially equivalent, and ISO 18369-2:2017
170 *Ophthalmic optics - Contact lenses - Part 2: Tolerances* and ANSI Z80.20-2016 for
171 tolerances.

172 **Submission Information:** Results summary and Declaration of Conformity (DoC)

173

174 2. **Test name:** Ultra Violet (UV) Transmittance (%)

175 **Methodology:** One of the following FDA currently-recognized consensus standards (as
176 applicable):

- 177 • ISO 18369-3 *Ophthalmic optics - Contact lenses - Part 3: Measurement methods*
- 178 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
179 *Standard Terminology, Tolerances, Measurements and Physicochemical*
180 *Properties*

181 **Performance Criteria (polymacon):** $\tau_{UVB} < 0.05 \tau_V$; $\tau_{UVA} < 0.50 \tau_V$

182 **Performance Criteria (etafilcon A):** $\tau_{UVB} < 0.05 \tau_V$; $\tau_{UVA} < 0.50 \tau_V$

183 **Performance Criteria (hioxifilcon D):** $\tau_{UVB} < 0.05 \tau_V$; $\tau_{UVA} < 0.50 \tau_V$

184 τ_V = luminous transmittance of the contact lens, τ_{UVB} and τ_{UVA} are the average ultraviolet
185 radiation transmittances of the contact lens, summated over the UVB (280 nm to 315 nm)
186 and the UVA (316 nm to 380 nm) wavelengths respectively

187 **Performance Criteria Source:** ANSI Z80.20-2016

188 **Additional Considerations:** Only needed for materials with added UV absorbers

189 **Submission Information:** DoC and Results Summary if using ISO 18369-3 for
190 methodology, otherwise DoC if using ANSI Z80.20 for the methodology

191

192 3. **Test name:** Refractive Index

193 **Methodology:** One of the following FDA currently-recognized consensus standards (as
194 applicable):

- 195 • ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical*
196 *properties of contact lens materials*
- 197 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
198 *Standard Terminology, Tolerances, Measurements and Physicochemical*
199 *Properties*

200 **Performance Criteria (polymacon):** 1.437 ± 0.005

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- 201 **Performance Criteria (etafilcon A): 1.402 ± 0.005**
202 **Performance Criteria (hioxifilcon D): 1.407 ± 0.005**
203 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
204 510(k) submissions previously found to be substantially equivalent, and ISO 18369-2:2017
205 *Ophthalmic optics - Contact lenses - Part 2: Tolerances for tolerances.*
206 **Submission Information:** Results summary and DoC
207
- 208 4. **Test name:** Water Content (%)
209 **Methodology:** One of the following FDA currently-recognized consensus standards (as
210 applicable):
- 211 • ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical*
212 *properties of contact lens materials*
 - 213 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
214 *Standard Terminology, Tolerances, Measurements and Physicochemical*
215 *Properties*
- 216 **Performance Criteria (polymacon): $38 \pm 2\%$**
217 **Performance Criteria (etafilcon A): $58 \pm 2\%$**
218 **Performance Criteria (hioxifilcon D): $54 \pm 2\%$**
219 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
220 510(k) submissions previously found to be substantially equivalent and ISO 18369-2:2017
221 *Ophthalmic optics - Contact lenses - Part 2: Tolerances for tolerances.*
222 **Submission Information:** Results summary and DoC
223
- 224 5. **Test name:** Specific Gravity
225 **Methodology:** Any standard methodology accepted
226 **Performance Criteria (polymacon): 1.124 ± 0.037**
227 **Performance Criteria (etafilcon A): 1.062 ± 0.041**
228 **Performance Criteria (hioxifilcon D): 1.214 ± 0.094**
229 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
230 510(k) submissions previously found to be substantially equivalent
231 **Submission Information:** Complete test report
232
- 233 6. **Test name:** Oxygen Permeability (Dk or $[\text{cm}^2/\text{s}][\text{ml O}_2/\text{ml x mmHg}]$)
234 **Methodology:** One of the following FDA currently-recognized consensus standards (as
235 applicable):
- 236 • ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical*
237 *properties of contact lens materials*
 - 238 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
239 *Standard Terminology, Tolerances, Measurements and Physicochemical*
240 *Properties*
- 241 **Performance Criteria (polymacon): $10.76 \times 10^{-11} \pm 20\%$**
242 **Performance Criteria (etafilcon A): $22.43 \times 10^{-11} \pm 20\%$**
243 **Performance Criteria (hioxifilcon D): $20.84 \times 10^{-11} \pm 20\%$**

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244 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
245 510(k) submissions previously found to be substantially equivalent and ISO 18369-2:2017
246 *Ophthalmic optics - Contact lenses - Part 2: Tolerances for tolerances.*

247 **Submission Information:** Results summary and DoC
248

249 7. **Test name:** Extractables (< 1% with water and hexane)

250 **Methodology:** One of the following FDA currently-recognized consensus standards (as
251 applicable):

252 • ISO18369-4 *Ophthalmic optics - Contact lenses - Part 4: Physicochemical*
253 *properties of contact lens materials*

254 • ANSI Z80.20 *American National Standard for Ophthalmics - Contact Lenses -*
255 *Standard Terminology, Tolerances, Measurements and Physicochemical*
256 *Properties*

257 **Performance Criteria (polymacon):** <1% extractables, hexane and water

258 **Performance Criteria (etafilcon A):** <1% extractables, hexane and water

259 **Performance Criteria (hioxifilcon D):** <1% extractables, hexane and water

260 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
261 510(k) submissions previously found to be substantially equivalent.

262 **Submission Information:** Results summary and DoC
263

264 **Mechanical Properties**
265

266 8. **Test name:** Modulus (MPa or N/mm²)

267 **Methodology:** One of the following FDA currently-recognized consensus standards (as
268 applicable):

269 • ASTM D882 *Standard Test Methods for Tensile Properties of Thin Plastic*
270 *Sheeting*

271 • ANSI Z80.20 - *American National Standard for Ophthalmics - Contact Lenses -*
272 *Standard Terminology, Tolerances, Measurements and Physicochemical*
273 *Properties*

274 **Performance Criteria (polymacon):** 0.62 ± 0.25 MPa

275 **Performance Criteria (etafilcon A):** 0.42 ± 0.09 MPa

276 **Performance Criteria (hioxifilcon D):** 0.36 ± 0.10 MPa

277 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
278 510(k) submissions previously found to be substantially equivalent.

279 **Submission Information:** Results summary and DoC
280

281 9. **Test name:** Tensile Strength (MPa or N/mm²)

282 **Methodology:** ASTM D882 *Standard Test Methods for Tensile Properties of Thin*
283 *Plastic Sheeting*

284 **Performance Criteria (polymacon):** 0.63 ± 0.11 MPa

285 **Performance Criteria (etafilcon A):** range of 0.07 to 0.41 MPa

286 **Performance Criteria (hioxifilcon D):** 0.65 ± 0.26 MPa

287 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
288 510(k) submissions previously found to be substantially equivalent.

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289 **Submission Information:** Results summary and DoC

290

291 10. **Test name:** Elongation at Break (%)

292 **Methodology:** ASTM D882 *Standard Test Methods for Tensile Properties of Thin*
293 *Plastic Sheeting*

294 **Performance Criteria (polymacon):** 240 ± 108%

295 **Performance Criteria (etafilcon A):** range of 50 to 340%

296 **Performance Criteria (hioxifilcon D):** 249 ± 69%

297 **Performance Criteria Source:** Criteria are based on aggregated data submitted to FDA in
298 510(k) submissions previously found to be substantially equivalent.

299 **Submission Information:** Results summary and DoC.

300

Packaging Solution

301

302

303 11. **Test name:** Packaging Solution pH

304 **Methodology:** Any standard methodology accepted

305 **Performance Criteria (all materials):** 7.2 – 7.4

306 **Performance Criteria Source:** Aggregated cleared 510(k) submissions

307 **Submission Information:** Results summary

308

309 12. **Test name:** Packaging Solution Osmolality (osmol/kg)

310 **Methodology:** Any standard methodology accepted

311 **Performance Criteria (all materials):** 280-320 osmol/kg

312 **Performance Criteria Source:** Aggregated cleared 510(k) submissions

313 **Submission Information:** Results summary

314

Sterilization

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317 13. **Test name:** Sterilization (devices labeled as sterile)

318 **Methodology:** FDA currently-recognized version of the following consensus standards

319 (as applicable):

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- 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>

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