K141280 510(K) SUMMARY

Date of the summary prepared: June 10, 2014

1 Establishment Information:
   Name                  Seinoh Optical Co. Ltd.
   Address              3F, No. 14, Wucyuan 3rd Rd., Sinjhuang Dist., New Taipei City 242, Taiwan, R.O.C.
   Phone No             886-2- 2298-8255
   Fax No.              886-2 –2298-8335

2 Owner:
   Company              Seinoh Optical Co. Ltd
   Name                 Vicent Hu
   Address              3F, No. 14, Wucyuan 3rd Rd., Sinjhuang Dist., New Taipei City 242, Taiwan, R.O.C.
   Phone No             886-2- 2298-8255 ext: 8858
   Fax No.              886-2 –2298-8335

3 US Agent:
   Company              ABAND INC.
   Address              5581 Daniels Street, Unit A, Chino, CA 91710, USA
   Phone No             (866)-886-8888 (Toll free)
   Fax No.              (909)-627-6207

4 Contact Person:
   Name                 Jennifer TING
   Phone No             886-2-82823192
   Fax No.              886-2-82867686
   e-mail:              jen.medical@msa.hinet.net

5 Device Identification:
   Proprietary Name iLen5 (ocufilcon D) Daily Wear Soft (Hydrophilic)
   Contact Lens
   Common Name         Soft (hydrophilic) Contact Lenses
   Classification Name Lenses, Soft Contact, Daily Wear (21 CFR 886.5925, Product Code LPL)
                        Lenses, Soft Contact, Daily Wear (Disposable),
                        (21 CFR 886.5925, Product Code MVN)
   Classification      II
6 Legally Marketed Equivalent Device:

Predicate Device Name Biomedics® 55 (ocufilcon D)
Manufacturer CooperVision, Inc.
510(k) Number K091339
Product Code LPL, MVN

7 Device Description

- The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens is a spherical lens with UV blocker.
- The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens is available in hemispherical shell.
- The lenses are made of HEMA hydrogel. The composition is 45% ocufilcon D and 55% water by weight when immersed in normal buffered saline solution.
- The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens is light blue tinted with "reactive BlueI9" for handling visibility purpose.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280-315nm and less than 50% in the UVA range of 316-380nm.
- The lens is supplied in a sterile state, packaged in a buffered saline solution.

8 Indication for Use:

The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-disease eyes in power from -20.00D to +20.00D. The lens may be worn by persons who exhibit refractive astigmatism of 2.0 diopters or less where the astigmatism does not interfere with visual acuity. The eye care practitioner may prescribe the lens for either single-use disposable wear or for scheduled replacement wear. When prescribed for scheduled replacement, the lens may be disinfected using a chemical (no heat) or hydrogen peroxide disinfecting system. As prescribed for single use daily disposable wear, patients are instructed to dispose of the lens at each removal. The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens help protect against transmission of harmful UV radiation to the cornea and into the eye.

9 Technological characteristics

The spherical lens design specification:
- Diameter 13 mm to 15 mm
• Center Thickness 0.08mm @ -3.00D
  (Varies with Power)
• Base Curve 8.2 mm to 9.2 mm
• Power -20.00D to +20.00D
  -6.00D to +6.00D (0.25D increments)
  +20.00D to +6.50D, -6.50D to -20.00D (0.50D increments)

The physical properties of the lenses are:
• Refractive index: 1.405 (hydrated)
• Light transmittance: > 95%
• Water content: 55% by weight in normal saline
• Oxygen permeability $20 \times 10^{-11}$ (Fatt method)

10 Comparison table:

The characteristic comparison to predicate device is summarized in the following table.

<table>
<thead>
<tr>
<th>Similarities</th>
<th>Device</th>
<th>Predicate (K091339)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Name</td>
<td>iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens</td>
<td>BIOMEDICS UV SPHERE Soft Contact Lenses</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Seinoh Optical Co. Ltd</td>
<td>CooperVision, Inc</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Daily Wear for Frequent/Planned Replacement Wear or for Daily disposable Wear</td>
<td>Daily Wear for Frequent/Planned Replacement Wear or for Daily disposable Wear</td>
</tr>
<tr>
<td>USAN Name</td>
<td>Ocufilcon D</td>
<td>Ocufilcon D</td>
</tr>
<tr>
<td>Material</td>
<td>Hydrogel</td>
<td>The same</td>
</tr>
<tr>
<td>Lens Design</td>
<td>Spherical</td>
<td>Spheric, aspheric, toric or multifocal</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II,</td>
<td>The same</td>
</tr>
<tr>
<td>Type</td>
<td>Group IV Ionic High Water</td>
<td>The same</td>
</tr>
<tr>
<td>Water Content</td>
<td>55%</td>
<td>55 %</td>
</tr>
<tr>
<td>Oxygen Permeability (DK, 35°C)</td>
<td>20</td>
<td>19.6</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Base Curve Range</th>
<th>8.2 mm to 9.2 mm</th>
<th>6.50 mm to 10.8 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
<td>13 to 15</td>
<td>12.5 – 18.0</td>
</tr>
<tr>
<td>Center Thickness</td>
<td>0.08mm @ -3.00D</td>
<td>Varies with power (0.025 mm to 0.40 mm)</td>
</tr>
<tr>
<td></td>
<td>(Varies with power)</td>
<td></td>
</tr>
<tr>
<td>Powers</td>
<td>-20.00D to +20.00D</td>
<td>-20.00 D to +20.00 D</td>
</tr>
<tr>
<td></td>
<td>-6.00D to +6.00D</td>
<td>Add powers: +0.25 D to +3.00 D</td>
</tr>
<tr>
<td></td>
<td>(0.25D increments)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>+20.00D to +6.50D, -6.50D to -20.00D</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.50D increments)</td>
<td></td>
</tr>
<tr>
<td>Replacement Schedule</td>
<td>Disposable or Daily wear</td>
<td>Disposable or Daily wear</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.405</td>
<td>1.41</td>
</tr>
<tr>
<td>Light Transmittance</td>
<td>&gt;95%</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>Method of Manufacture</td>
<td>Cast-Molded</td>
<td>The same</td>
</tr>
<tr>
<td>Surfactant in the final Product Saline</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterilization</td>
<td>steam</td>
<td>The same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Blister pack</td>
<td>The same</td>
</tr>
<tr>
<td>Blue handling tint</td>
<td>Yes, reactive Blue19</td>
<td>Yes, Entrapment Dye</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mechanical Strength</th>
<th>Device</th>
<th>Predicate (K013649)</th>
<th>Predicate (K000384)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>iLens</td>
<td>Sauflon 55 UV (methaflicon A)</td>
<td>Frequency 55</td>
</tr>
<tr>
<td>Tensile strength (Mpa)</td>
<td>0.43</td>
<td>1.47</td>
<td>0.66</td>
</tr>
<tr>
<td>Modulus (Mpa)</td>
<td>0.57</td>
<td>0.52</td>
<td>0.48</td>
</tr>
<tr>
<td>Elongation at break (%)</td>
<td>55.8</td>
<td>280</td>
<td>179</td>
</tr>
<tr>
<td>toughness (J/m³)</td>
<td>0.21</td>
<td>1.39</td>
<td>0.38</td>
</tr>
<tr>
<td>Manufacturing method</td>
<td>Cast Mold</td>
<td>Cast Mold</td>
<td>Cast Mold</td>
</tr>
</tbody>
</table>

Mechanical Strength Devices and Predicates Table
11 Nonclinical Tests Performed

11.1 Physiochemical studies were conducted according to ISO 18369 First edition 2006-08-15, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.

11.2 Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

12 Clinical Studies
The technical characteristics, formulation, manufacturing, and sterilization processes of the subject device are equivalent to ocufilcon D soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

13 Conclusion
Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens” is as safe, as effective and perform as well as the predicate device.
July 18, 2014

Seinoh Optical Co. Ltd.
c/o Jennifer Ting
Jens Medical Consulting
6F No. 39 Ln. 224, Jixian Road
Luzhou Distr. 247. New Taipei City
Taiwan ROC

Re: K141280
Trade/Device Name: iLens (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: LPL, MVN
Dated: May 20, 2014
Received: May 22, 2014

Dear Ms. Ting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Ms. Jennifer Ting

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-disease eyes in power from -20.00D to +20.00D. The lens may be worn by persons who exhibit refractive astigmatism of 2.0 diopters or less where the astigmatism does not interfere with visual acuity. Eye care practitioners may prescribe the lens for either single-use disposable wear or for frequent replacement wear. When prescribed for frequent replacement wear, the lens may be disinfected using a chemical or hydrogen peroxide disinfecting system. As prescribed for single use daily disposable wear, patients are instructed to dispose of the lens at each removal. The iLens® Daily Wear Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joseph C. Hutter -S
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