JUL 18 2014

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	iLens® (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 Blue19" 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 20×10^{-11} (Fatt method)

10 Comparison table:

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

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

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

Mechanical Strength	Device	Predicate (K013649)	Predicate (K000384)
Product Name	iLens	Sauflon 55 UV (methafilcon A)	Frequency 55
Tensile strength (Mpa)	0.43	1.47	0.66
Modulus (Mpa)	0.57	0.52	0.48
Elongation at break (%)	55.8	280	179
toughness (J/m^3)	0.21	1.39	0.38
Manufacturing method	Cast Mold	Cast Mold	Cast Mold

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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.

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" (21CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141280

Device Name
iLens® (ocufilcon D) Daily Wear Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*
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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

Joseph C. Hutter -S
2014.07.15 16:00:24 -04'00'

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