June 29, 2018

Largan Medical Co. Ltd.
% Jennifer Ting
Project Manager
Jens Medical Consulting Ltd.
6F, No. 39, Ln 224, Jixian Rd.,
Luzhou Dist. 247 New Taipei
City, Taiwan R.O.C.

Re: K181232
Trade/Device Name: Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens, Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism, Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: May 7, 2018
Received: May 9, 2018

Dear Jennifer 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J Angelo Green -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181232

Device Name
Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for astigamtism
Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for presbyopia

Indications for Use *(Describe)*
The Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is a daily wear soft contact lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or non-aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism is indicated daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters and astigmatic corrections are from -0.25 to -5.00 diopters.

The Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia is indicated daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters with add powers from +0.25 to +3.50 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 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/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for single-use disposable wear, the lens is to be discarded after each removal, therefore no cleaning or disinfecting is required. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K181232

510(k) Summary

Preparation Date: June 23, 2018

1.1 Establishment Information:

Name	**Largan Medical Co. Ltd.**
Owner	Adam Lin
Title	CEO
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E-mail	info@larganmed.com.tw

1.2 Contact Person:

Contact Name	Amy Tien
Phone No.	886-4-3600-0203
Fax No.	886-4-3601-0203
E-mail	amytien@larganmed.com.tw

1.3 Device Identification:

Proprietary Name	Largan 55 UV (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
Regulation Number	CFR 886.5925
Review Panel	Ophthalmic
Product Code	LPL/MVN

1.4 Legally Marketed Equivalent Device:

Predicate Device Name	Biomedics 55 (ocufilcon D) Soft (hydrophilic) Contact Lens.
Manufacturer	CooperVision, Inc.
510(k) Number	K091339
Product Code	LPL/MVN

1.5 Device Description

The Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is in hemispherical flexible shells for myopia, hyperopia, astigmatisam and Presbyopia. The lens is made from HEMA containing UV blocker. The composition of the lens is 45% ocufilcon D and 55% water. The lens is tinted with “Reactive Blue 246” to make a light blue color for handling visibility purpose. A Benzophenone 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. It is supplied in a sterile package with buffered saline solution.

1.6 Indication for Use:

The **Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens** is a daily wear soft contact lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or non-aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The **Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism** is indicated daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters and astigmatic corrections are from -0.25 to -5.00 diopters.

The **Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia** is indicated daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters with add powers from +0.25 to +3.50 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 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/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for single-use disposable wear, the lens is to be discarded after each removal, therefore no cleaning or disinfecting is required. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

1.7 Technological characteristic

Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens characteristics:

- Diameter Range：13.0 to 15.0 mm
- Base Curve：8.0 to 9.0 mm
- Center Thickness：0.084 mm for -3.00D (varies with power)
- Power：+3.00 to -10.00 D

Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism characteristics:

- Diameter Range：13.0 to 15.0 mm
- Base Curve：8.0 to 9.0 mm
- Center Thickness：0.084 mm for -3.00D (varies with power)
- Power：+3.00 to -10.00 D
- Cylinder: -0.25D ~ -5.00 D
- Axis: 10º to 180º (in 10º increments)

Largan 55 UV (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia characteristics:

- Diameter Range：13.0 to 15.0 mm
- Base Curve：8.0 to 9.0 mm
- Center Thickness：0.130 mm for -3.00D (varies with power)
- Power：+3.00 to -10.00 D
- Additional Powers: +0.25D ~ +3.50D

1.8 Comparison table:

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

Similarities and differences		
Item	**Device**	**Predicate (K091339)**
Product Name	Largan 55 UV daily wear soft contact lens	Biomedics Daily Wear Soft Contact Lens
Manufacturer	Largan Medical Co. Ltd	Cooper Vision., Inc.
Intended Use	Myopia, Hyperopia, astigmatism, Presbyopia	myopia, hyperopia, astigmatism, Presbyopia
Lens Design	aspherical, toric, or multifocal	Spherical, aspherical, toric, multifocal
Replacement Schedule	Daily Wear	The same
Chemical composition	Ocufilcon D	The same
Classification	Group IV (ionic, High water)	The same
Water Content	55 %	55%
Oxygen Permeability (DK, 35℃)	19.6 (Fatt method)	19.6
Base Curve Range (mm)	8.0~9.0	6.50 to 10.8
Diameter (mm)	13.0~15.0	12.8 to 18.0
Center Thickness	Varies with design and power (0.084 mm at -3.00D)	0.025-0.40 mm (Varies with power)
Powers	-10.00D to +3.00D	-20.00 to +20.00D
Add Powers	+0.25E to +3.50D	+0.25D to +3.00D
Cylinder Power	-0.25D to -5.00D	-0.25D to -10.00D
Axis	1° to 180°	1° to 180°
Refractive Index	1.405	1.41
Light Transmittance	90%	>95%
Blue handling tint	Reactive Blue 246	Entrapment Dye

1.9 Nonclinical Tests Performed

1.9.1 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.

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

1.10 Clinical Studies

The technical characteristics and formulation of the subject device are equivalent to Biomedics 55 Daily Wear Contact Lens (K091339) current marketed by CooperVision Inc., therefore no clinical data is required.

1.11 Conclusion

Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “Largan 55 UV daily wear soft (hydrophilic) contact lens” is as safe, as effective and performs as well as the predicate device.