November 1, 2018

Largan Medical Co., Ltd.
Amy Tien
RA Specialist
2F., No. 14, 23rd Rd., Taichung Industrial Park,
Nantun Dist., Taichung, 40850 Taiwan

Re: K182523
Trade/Device Name: Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 30, 2018
Received: September 13, 2018

Dear Amy Tien:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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

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)*
K182523

Device Name
Largan 55 UV Color (Ocufilcon D) Daily Wear Soft Contact Lens

Indications for Use *(Describe)*
The Largan 55 UV Color (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 Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism is indicated for 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 Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia is indicated for 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 +0.75 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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K182523

510(k) Summary

Preparation Date: August 30, 2018

1.1 Establishment Information:

Name	Largan Medical Co. Ltd.
Owner	Adam Lin
Title	CEO
Address	2F., No. 14, 23rd Rd., Taichung Industrial Park, Nantun Dist., Taichung, 40850, Taiwan
Phone No.	886-4-3600-0203
Fax No.	886-4-3601-0203
E-mail	info@larganmed.com.tw

1.2 Contact Person:

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

1.3 Device Identification:

Proprietary Name	Largan 55 UV Color (Ocufilcon D) Daily Wear Soft 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:

1.4.1 Lens material, lens design, and intended use:

Predicate 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.

Manufacturer	Largan Medical Inc.
510(k) Number	K181232
Product Code	MVN;LPL

1.4.2 Color additives:

Predicate Device Name	BIOMEDICS® UV Colors (Ocufilcon D) Soft (Hydrophilic) Contact Lens
Manufacturer	Ocular Sciences Inc.
510(k) Number	K013377
Product Code	LPL

1.5 Device Description

The Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is available in hemispherical flexible shells for myopia, hyperopia, astigmatisam and presbyopia. The Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is an aspherical design contact lens. The lens material (Ocufilcon D) is a hydrophilic co-polymer by cross-linking 2-Hydroxyethyl methacrylate (HEMA), Methacrylic acid (MAA) and Ethylene Glycol Dimethacrylate (EGDMA). The hydrated lens consists of 45.0% (Ocufilcon D) and 55.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280 to 315nm and less than 50% in the UVA range of 315 to 380 nm. The lenses contain a combination of the following color additives: Phthalocyanine green, Carbazole violet, [Phthalocyaninato (2-)] copper, Titanium dioxide, Iron oxides, Mica-based pearlscent pigment, and Chromium-cobalt-aluminum oxide. All color additives used are listed in 21 CFR 73 Subpart D and 74 Subpart D.

1.6 Indication for Use:

The **Largan 55 UV Color (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 Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism** is indicated for 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 Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia** is indicated for 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 +0.75 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 Color (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 -3.00 D
- Power：+3.00 to -10.00 D

Largan 55 UV Color (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 -3.00 D
- Power：+3.00 to -10.00 D
- Cylinder: -0.25D to -5.00 D
- Axis: 10º to 180º (in 10º increments)

Largan 55 UV Color (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 -3.00 D
- Power：+3.00 to -10.00 D
- Additional Powers:+0.75 D to +3.50D

1.8 Comparison table:

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

Similarities and differences			
Item	**Device**	**Predicate (K181232)**	**Predicate (K013377)**
Product Name	Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens	Largan 55 UV (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens	BIOMEDICS® UV Colors (Ocufilcon D) Soft (Hydrophilic) Contact Lens
Manufacturer	Largan Medical Inc.	The same	Ocular Sciences Inc.
Intended Use	Myopia, Hyperopia, astigmatism, Presbyopia	The same	Myopia, Hyperopia
Lens Design	Aspherical, toric, or multifocal	The same	Spherical
Replacement Schedule	Daily Wear	The same	The same
Chemical composition	Ocufilcon D	The same	The same
Classification	Group IV (Ionic, High water)	The same	The same
Water Content	55 % (>50%),	The same	The same
Oxygen Permeability (DK, 35℃)	19.6 (Fatt method)	The same	The same
Base Curve Range (mm)	8.0~9.0	The same	8.0~9.2
Diameter (mm)	13.0~15.0	The same	12.0~15.0
Center Thickness	Varies with design and power (0.084 mm at -3.00D)	The same	0.025mm~40mm
Powers	-10.00D to +3.00D	The same	-20.00D to +10.00D
Refractive Index	1.405	The same	The same

Light Transmittance	90%	The same	97%
Color additives	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)]copper ● Titanium dioxide ● Iron oxides ● Chromium-cobalt-aluminum oxide ● Mica-based pearlscent pigment	Reactive Blue 246	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)]copper ● Titanium dioxide ● Iron oxides ● Chromium-cobalt-aluminum oxide

1.9 Nonclinical Tests Performed

1.9.1 Physiochemical studies were conducted according to ISO 18369, 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 lens material is the same as Largan 55 UV (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens (K181232). The color additives of the subject device are equivalent to BIOMEDICS® UV Colors (Ocufilcon D) Soft (Hydrophilic) Contact Lens (K013377). Therefore, no clinical data is required.

1.11 Conclusion

Comparison to the predicate devices for chemical composition, physical and optical properties, it shows that " Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens " is as safe, as effective and performs as well as the predicate devices