April 1, 2021

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

Re: K202129
Trade/Device Name: Largan DB / DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens,
Largan DB / DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism,
Largan DB / DB Color (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: February 25, 2021
Received: February 26, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Angelo Green
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K202129

Device Name
Largan DB/ DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Largan DB/ DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for ASTIGMATISM
Largan DB/ DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for PRESBYOPIA

Indications for Use *(Describe)*
The Largan DB (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens/ Largan DB Color (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is a daily wear soft (hydrophilic) contact lens indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic 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 DB (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism/ Largan DB Color (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 DB (ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia/ Largan DB Color (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. When prescribed for frequent replacement, it is recommended that the lenses be discarded and replaced with a new lens not more than every 1 month. However, the Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon the response of the patient. The Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is also intended to enhance or alter the apparent color of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Preparation Date: March 22, 2021

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 DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens; Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens; Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism; Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism; Largan DB (Ocufilcon D) Daily Wear Soft Contact Lens for Presbyopia; Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia
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	CRF 886.5925
Review Panel	Ophthalmic
Product Code	LPL;MVN

1.4 Legally Marketed Equivalent Device:

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/ Largan 55 UV Color(Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens; Largan 55 UV Color(Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism; Largan 55 UV Color(Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia
Manufacturer	Largan Medical Co. Ltd.
510(k) Number	K181232/ K182523
Product Code	LPL; MVN

1.5 Device Description

The Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens/ Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is available as an aspherical lens, multifocal lens and as an astigmatic (toric) lens. The lens material (Ocufilcon D) is a hydrophilic co-polymer cross-linked with Ethylene Glycol Dimethacrylate (EGDMA). The hydrated lens consists of 45.0% (Ocufilcon D) and 55.0% water by weight of immersed in normal saline

The Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens, Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens, Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for ASTIGMATISM, Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for ASTIGMATISM, Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for PRESBYOPIA and Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for PRESBYOPIA is a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera. UV absorbing monomer is used to filter UV radiation. Reactive Yellow 15 is used to tint the lens. The average transmittance characteristics (the thinnest lens measured by spectrophotometry as stated in ISO 18369) are less than 5% in the UVB range of 280 to 315 nm and less than 50% in the UVA range of 315 to 380 nm. The lenses are available with a visibility-handling tint or with a decorative tint intended to enhance or alter the apparent color of the eye.

1.6 Indication for Use:

The **Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens/ Largan DB 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 aphakic 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 DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism/ Largan DB Color (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 DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia/ Largan DB Color (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. When prescribed for frequent replacement, it is recommended that the lenses be discarded and replaced with a new lens not more than every 1 month. However, the Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon the response of the patient. The Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is also intended to enhance or alter the apparent color of the eye.

1.7 Technological characteristic

Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens/ Largan DB 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 -3.00D (varies with power)
- Power：+3.00 to -10.00 D

Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism/ Largan DB 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 -3.00D (varies with power)
- Power：+3.00 to -10.00 D
- Cylinder: -0.25D ~ -5.00 D
- Axis: 10º to 180º (in 10ºincrements)

Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia/ Largan DB 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 -3.00D (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 devices is summarized in the following table.

Similarities and differences			
Item	**Device**	**Predicate (**K181232)	**Predicate (**K182523)
Product Name	Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens	Largan 55 UV (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens	Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Manufacturer	Largan Medical Co. Ltd.	The same	The same
Intended Use	Myopia, Hyperopia, astigmatism, Presbyopia	The same	The same
Indication for use	The **Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens/ Largan DB 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 same	The same

	The **Largan DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism/ Largan DB Color (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 DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia/ Largan DB Color(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. When prescribed for frequent replacement, it is recommended that the lenses be discarded and replaced with a new lens not more than every 1 month. However, the Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon response of the patient.		

	The Largan DB Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens is also intended to enhance or alter the apparent color of the eye.		
Lens Design	Aspherical, toric, or multifocal	The same	The same
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 %	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	The same
Diameter (mm)	13.0~15.0	The same	The same
Center Thickness	Varies with power	The same	The same
Powers	-10.00D to +3.00D	The same	The same
Refractive Index	1.405	The same	The same
Light Transmittance	90%	The same	The same
Color additives	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)]copper ● Titanium dioxide ● Iron oxides ● Chromium-cobaltaluminum oxide ● Mica-based pearlscent pigment ● Yellow 15	● Reactive Blue 246	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)]copper ● Titanium dioxide ● Iron oxides ● Chromium-cobaltaluminum oxide ● Mica-based pearlscent pigment

Method of Manufacture	Cast Molded	The same	The same
Packaging saline	Saline solution with sodium hyaluronate and poloxamer kolliphor P407	The same	The same

1.9 Nonclinical Tests Performed

1.9.1 Physiochemical studies were conducted according to ISO 18369-4 second edition 2017-08, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specification for the lenses.

1.9.2 Biocompatibility studies including cytotoxicity, acute ocular irritation, and acute systemic injection toxicity studies of subject lenses and primary package (polypropylene blister and aluminum foil) were conducted according to ISO 10993 series biocompatibility standard to assess the biological safety of the medical device and all of them are non-toxic and biocompatible. Biocompatibility tests following referenced standards as below:

1. ISO 10993 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity. (2009)
2. ISO 10993 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization. (2010)
3. ISO 10993 Biological evaluation of medical devices- Part 11: Tests for Systemic toxicity. (2006)
4. ISO 10993 Biological evaluation of medical devices- Part 12: Sample preparation and reference materials. (2012)

1.10 Clinical Studies

The technical characteristics, formulation, manufacturing process of the subject device are equivalent to Largan 55 UV (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens (K181232) and Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens (K182523) current marketed by Largan Medical Co., Ltd, 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 DB (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens" demonstrates substantial equivalence as the predicate device.