February 04, 2025

Largan Medical Co., Ltd.
Shih-Min Chen
RA Specialist
2F., No. 14, 23rd Rd., Taichung Industrial Park, Nantun Dist
Taichung, 40850
Taiwan

Re: K242916
Trade/Device Name: Largan U38 Color (Polymacon) 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: September 04, 2024
Received: December 26, 2024

Dear Shih-Min Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

J Angelo Green -S

J. Angelo Green, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242916

Device Name

Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*

The Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens is a daily wear soft contact lens indicated for daily wear to enhance or alter the apparent color of the eye and/or 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.
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K242916

510(k) Summary

Preparation Date: May 23, 2024
Updated Date: Jan 31, 2025

1 Establishment Information:

Name	Largan Medical Co. Ltd.
Owner	Adam Lin
Title	CEO
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2 Contact Person:

Phone No.	886-4-3600-0203 #20246
Fax No.	886-4-3601-0203
Contact Name	Shih-min Chen
E-mail	shihminchen@larganmed.com.tw

3 Device Identification:

Proprietary Name	Largan U38 Color (Polymacon) 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

4 Predicate Device:

4.1 Legally Marketed Equivalent Device (Primary):

Predicate Device Name	Largan U38 (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens
Manufacturer	Largan Medical Co. Ltd.
510(k) Number	K182674
Product Code	LPL; MVN

4.2 Legally Marketed Equivalent Device (Secondary):

Predicate Device Name	Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
Manufacturer	Largan Medical Co. Ltd.
510(k) Number	K182523
Product Code	LPL; MVN

5 Device Description

The Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens is available in hemispherical flexible shells for myopia. The Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens is an aspherical design contact lens. The lens material (Polymacon) is a hydrophilic co-polymer by cross-linking 2-Hydroxyethyl methacrylate (HEMA), and Ethylene Glycol Dimethacrylate (EGDMA). The hydrated lens consists of 62.0% (Polymacon) and 38.0% water by weight of saline immersed in normal saline. A light blue color tinted with “reactive Blue 247” is for handling visibility purpose. 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 (Red, Yellow and Black),and Mica-based pearlscent pigment (Gold, Silver and Red). All color additives used are listed in 21 CFR 73 subpart D and 74 subpart D. It is supplied in a sterile package with buffered saline solution.

6 Indications for Use

The Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens is a daily wear soft contact lens indicated for daily wear to enhance or alter the apparent color of the eye and/or 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.

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.

7 Technological characteristic

Largan U38 Color (Polymacon) 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：0.100 mm for -3.00 D
- Power：+3.00 to -10.00 D

8 Comparison table

Item	Subject Device	Predicate (Primary)	Predicate (Secondary)
Product Name	Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens	Largan U38 (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens	Largan 55 UV Color (Ocufilcon D) Daily Wear Soft (hydrophilic) Contact Lens
K number	K242916	K182674	K182523
Product code	LPL; MVN	LPL; MVN	LPL; MVN
Manufacturer	Largan Medical Co. Ltd.	Identical	Identical
Intended Use	Myopia, Hyperopia	Identical	Identical
Indication for use	The Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens is a daily wear soft contact lens indicated for daily wear to enhance or alter the apparent color of the eye and/or 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. 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.	The Largan U38 (Polymacon) 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. 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.	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. 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.

Lens Design	Aspherical	Identical	Identical
Replacement Schedule	Daily Wear/ frequent replacement	Identical	Identical
Chemical composition	Polymacon	Identical	Ocufilcon D
Classification	Group I (Nonionic, Low water)	Identical	Group IV (Ionic, High water)
Water Content	38% (<50%)	Identical	55%
Oxygen Permeability (DK, 35℃)	8.0 (Fatt method)	Identical	19.6 (Fatt method)
Base Curve Range(mm)	8.0~9.0	Identical	Identical
Diameter (mm)	13.0~15.0	Identical	Identical
Center Thickness	Varies with design and Power (0.100 mm at -3.00D)	Identical	Identical
Powers	-10.00D to +3.00D	Identical	Identical
Refractive Index	1.435	Identical	1.405
Light Transmittance	90%	Identical	Identical
Color additives	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)] copper ● Titanium dioxide ● Iron oxides ● Mica-based pearlscent pigment	Reactive Blue 247	● Phthalocyanine green ● Carbazole violet ● [Phthalocyaninato(2-)] copper ● Titanium dioxide ● Iron oxides ● Chromium-cobalt-aluminum oxide ● Mica-based pearlscent pigment
Method of Manufacture	Cast Molded	Identical	Identical

9 Performance data

The following performance data were provided in support of the substantial equivalence determination.

9.1 Non-Clinical Tests

The non-clinical tests had been performed to demonstrate the safety and effectiveness of Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens. Non-Clinical testing performed includes:

- Back Vertex Power
- Radius of Curvature
- Overall Diameter
- Center Thickness
- Inspection of Edges, Inclusions and Surface Imperfections
- pH values
- Osmotic Pressure
- Refractive Index
- Transmittance
- Water content
- Oxygen permeability
- Extractables
- Mechanical properties
- Leachability of color additives

9.2 Biocompatibility Test

The biocompatibility evaluation for the Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens was conducted in accordance with the FDA "Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses (1994)," as recognized by FDA. The packaging solution is identical to the predicate devices (K182674 and K182523). Additional testing of lens materials and primary packaging included:

- In-Vitro Cytotoxicity was performed on extracts of the finished contact lenses and the primary packaging in accordance with ISO 10993-5 with results indicating that the device is non-cytotoxic.
- Ocular irritation testing was performed on extracts of the finished contact lens and the primary packaging in accordance with ISO 10993-10 and resulted in no ocular irritation.
- Acute systemic toxicity was performed on the extracts of the finished contact lenses and the primary packaging in accordance with ISO 10993-11 and no acute systemic toxicity was found.
- Skin Sensitization Study in Guinea Pigs performed on the extracts of the finished contact lenses in accordance with ISO 10993-10 and no skin sensitization was found.

10 Conclusion

Comparison to the predicate devices for chemical composition, physical and optical properties, it shows that "Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens" is as safe, as effective and performs as well as the predicate devices.