May 21, 2026

Pegavision Corporation
Estela Lin
Regulatory Affair Engineer Supervisor
2F-1, No. 5, Shing Yeh St., Guishan Dist
Taoyuan City, 33341
Taiwan

Re: K253352
Trade/Device Name: Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: September 30, 2025
Received: April 16, 2026

Dear Estela Lin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253352

Please provide the device trade name(s).

Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses;
Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses

Please provide your Indications for Use below.

Sphere/ Asphere
Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia) in aphakic or non-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in powers ranging from +6.00D to -12.00D.

Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia) in aphakic or non-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in powers ranging from +6.00D to -12.00D.
The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are intended for single-use disposable wear.

Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses are intended for frequent/planned replacement wear with cleaning, rinsing, disinfecting and scheduled replacement as prescribed by the eye care professional. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical (not heat) lens care system only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY for K253352

The following 510(K) Summary is being submitted as required by 21CFR 807.92(a).

Submitter Information

Company:	PEGAVISION CORPORATION No.5, Shing Yeh St., Guishan Dist., Taoyuan City 333, Taiwan
Contact Person:	Estela Lin, Regulatory Affair Engineer Supervisor
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Date Prepared:	September 3, 2025

Identification of Device

Trade Name:	Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses
Common Name:	Soft (hydrophilic) Contact Lenses (daily wear)
Classification Name:	Lenses, Soft Contact, Daily Wear 21CFR. 886.5925, Product Code LPL Lens. Soft Contact (Disposable). 21CFR. 886.5925, Product Code MVN
FDA Classification:	Class II
Predicate Device:	K232839, Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear

Description of Device

Pegavision (Polymacon) Family lenses are clear or visibility-tinted with a UV blocker, and are available as spherical lenses or aspherical lenses. When tinted, the lens is visibly tinted with color additive ”Reactive Blue 19”, as listed in 21 CFR 73.3121. The non-ionic lens material consists of a polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA) via photo-

polymerization. The copolymer consists of 62% Polymacon and 38% water by weight when immersed in normal buffered saline solution. There are three types of buffer solutions: a basic borate-buffered solution; a solution containing Tween 80, Polyethylene Glycol, and Sodium Hyaluronate; and a solution containing the same components with the addition of Cyanocobalamin. The lens further contains a benzotriazole UV absorbing monomer and thus is able to block UV radiation. The UV blocking averages 95% in the UVB range of 280 nm to 315 nm and 50% in the UVA range of 315 nm to 380 nm. The Polymacon name has been adopted by the United States Adopted Names Council (USAN).

When the lenses are printed color design, the pigments for specific pattern formation in lenses are for cosmetic purpose. The color additives used in the lenses are listed in 21 CFR part 73 and part 74. The color additives used in the decorative lens models within the scope of this 510(k) are listed in the following table.

Item	Chemical Name	FDA Standard
1	[Phthalocyaninato(2-)] copper	21 CFR section 74.3045
2	Phthalocyanine Green	21 CFR section 73.3124
3	Carbazole violet	21 CFR section 73.3107
4	Yellow Iron Oxide	21 CFR section 73.3125
5	Red Iron Oxide	21 CFR section 73.3125
6	Black Iron Oxide	21 CFR section 73.3125
7	Titanium Dioxide	21 CFR section 73.3126
8	Mica-based pearlescent pigments	21 CFR section 73.3128

Indications for use

Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses
Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses

- **Sphere and Asphere**

  The lenses are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia) in aphakic or non-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in powers ranging from +6.00D to -12.00D.

Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses
Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses

- **Sphere and Asphere**
  The lenses are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia) in aphakic or non-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in powers ranging from +6.00D to -12.00D. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are intended for single-use disposable wear.

Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses are intended for frequent/planned replacement wear with cleaning, rinsing, disinfecting and scheduled replacement as prescribed by the eye care professional. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical (not heat) lens care system only.

Technological characteristics studies

The technological characteristics of the Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses, as compared to the predicate devices, are summarized in the following table.

Device Name/ Subgroups	Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
510(k) Number	Proposed Subject Device	K232839
USAN Name	Polymacon	Polymacon
FDA Category (Group)	Group 1	Group 1
Lens Design	Sphere and Asphere	Asphere
Expected Clinical Performance	Vision Correction	Vision Correction
Indications	Daily wear	Daily wear
Production Method	Cast-molding	Cast-molding
Sterilization Method	Moist Heat	Moist Heat
Lens Color	Clear or Tint, Color	Clear or Tint
UV-blocking	Class II	Class II
Water Content	38%	38%
Oxygen Permeability	10.22×10^{-11} (cm^2/s) [$mlO_2/(ml \times mmHg)$]	13.5×10^{-11} (cm^2/s) [$mlO_2/(ml \times mmHg)$]
Powers	+6.00D ~ -12.00D	+20.00D ~ -20.00D
Refractive Index	1.438	1.440

Summary of Clinical Study

Polymacon lenses have been used widely. Their safety and effectiveness have been well documented. Their safety and effectiveness can be further exemplified by the lenses cleared by FDA. As the material and manufacturing process used in the subject device are identical to those of the predicate device (K232839), no additional clinical data are required to support this 510(k) premarket notification.

Non-clinical Study

All tests were conducted in accordance with the May 1994 FDA guidance title

Premarket Notification 510(K) Guidance Document for Class II Contact Lenses. The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses.

Non-Clinical testing performed includes:

- Physicochemical Properties Test
  - Refractive Index
  - Oxygen Permeability
  - Water content
  - Extractables
  - Mechanical Property
  - Light Transmittance
- Biocompatibility Test

Contact Lenses
The biocompatibility testing has been verified using the worst-case lenses with highest concentration of each color additives. • Cytotoxicity Test (ISO 10993-5) • Ocular Irritation Test (ISO 10993-10/ ISO 10993-23) • Acute Systemic Toxicity Test (ISO 10993-11)
Packaging Solution
Saline A: The materials have the same formulation as the packaging solution used in K232649, no additional biocompatibility testing was required. Saline B and Saline C: • Cytotoxicity Test (ISO 10993-5) • Ocular Irritation Test (ISO 10993-10/ ISO 10993-23)
Primary Packaging
The devices use the same primary packaging materials as the K232649. The biocompatibility has been verified, no additional biocompatibility testing was required.

- Shelf Life Test and Sterility Test

Substantial Equivalence Statement

Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses,

Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses have the same indication for use and USAN name as the predicate device Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K232839), as well as same manufacturing techniques. Therefore, the information submitted supports the substantial equivalency.

Conclusion

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses, Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses. It is concluded that the lenses are as safe, as effective and perform as well as the predicate device.