July 2, 2025

Pegavision Corporation
Estela Lin
Official Correspondent
2F-1, No. 5, Shing Yeh St., Guishan Dist
Taoyuan City, 33341
Taiwan

Re: K243868
Trade/Device Name: Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses; Pegavision (Toufilcon B) 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: November 25, 2024
Received: December 17, 2024

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 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,

ELISSA WONG -S
Digitally signed by ELISSA WONG -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243868

Device Name

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses;
Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*

Sphere/ Asphere
Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) 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 spherical powers ranging from +6.00D to -12.00D .

Toric
Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses with Toric designs are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic or non-aphakic persons with non-diseased eyes. The lens may be prescribed in spherical powers ranging from +6.00D to -12.00D and astigmatic corrections from -0.25D to -3.50D.

Multifocal
Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses with Multifocal designs are indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) with presbyopia in aphakic or non-aphakic person with non-diseased eyes who may have +0.25D to +3.00D of ADD powers or less. The lens may be prescribed in spherical powers ranging from +6.00D to -12.25D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses are intended for single-use disposable wear.
Pegavision (Toufilcon B) 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K243868

510(k) SUMMARY

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

Submitter Information

Company:	PEGAVISION CORPORATION 2F-1 No.5, Shing Yeh St., Guishan Dist., Taoyuan City 333, Taiwan
Contact Person:	Estela Lin, Regulatory Affair Engineer Supervisor
Phone:	886-3-329-8808
Fax:	886-3-329-8897
E-Mail:	EstelaLin@pegavision.com
Date Prepared:	June 6, 2025

Identification of Device

Trade Name:	Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses Pegavision (Toufilcon B) 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:	K052560, Biofinity (Comfilcon A) Soft Contact Lens

Description of Device

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses are clear and visibility tint with UV blocker are available as a spherical lens. The lens material, Toufilcon B is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA), N-Vinyl-2-Pyrrolidinone (NVP), N,N-Dimethylcarylamide (DMA), Methacrylic Acid (MAA), (3-Methacryloxy-2-hydroxypropoxy)propyl-bis(trimethylsiloxy)methylsilane (SiGMA) and Polydimethylsiloxane macromer (monofunctional Polydimethylsiloxane) (PDMS macromer), cross-linked with Ethylene glycol dimethacrylate (EGDMA) and

Triallyl isocyanurate (TAIC) via photo-polymerization. The copolymer consists 50% Toufilcon B and 50% water by weight when immersed in buffered borate solution. The lens further contains a benzotriazole UV absorbing monomer and thus is able to block UV radiation. The lens is visibly tined with "Reactive Blue19" color additive, 21 CFR part 73.3121. 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 Toufilcon B name has been adopted by the United States Adopted Names Council (USAN).

Indications for use

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses
Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses

- **Sphere and Asphere**

  Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) 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 spherical powers ranging from +6.00D to -12.00D.

- **Toric**

  Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses with Toric designs are indicated for daily wear for vision correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic or non-aphakic persons with non-diseased eyes. The lens may be prescribed in spherical powers ranging from +6.00D to -12.00D and astigmatic corrections from -0.25D to -3.50D.

- **Multifocal**

  Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses with Multifocal designs are indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) with presbyopia in aphakic or non-aphakic person with non-diseased eyes who may have +0.25D to +3.00D of ADD powers or less. The

lens may be prescribed in spherical powers ranging from +6.00D to -12.25D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses are intended for single-use disposable wear.

Pegavision (Toufilcon B) 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 (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses, as compared to the predicate devices, are summarized in the following table.

Device Name/ Subgroups	Subject Device	Predicate Device
	PEGAVISION (Toufilcon B) Soft (Hydrophilic) Contact Lenses PEGAVISION (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses	Biofinity (Comfilcon A) Soft Contact Lens
510(k) Number	New Device	K052560
USAN name	Toufilcon B	Comfilcon A
FDA Category (Group)	Group 5	Group 5
Intended use	Spherical and Aspherical, Toric, Multifocal	Spherical and Aspherical, Toric, Multifocal
Expected clinical performance	Eye for vision correction	Eye for vision correction
Indications	Daily wear	Daily wear

Device Name/ Subgroups	Subject Device	Predicate Device
	PEGAVISION (Toufilcon B) Soft (Hydrophilic) Contact Lenses PEGAVISION (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses	Biofinity (Comfilcon A) Soft Contact Lens
Replacement schedule	Daily/Bi-weekly/Monthly	Monthly
Production Method	Cast-molding	Cast-molding
Sterilization Method	Moist Heat	Moist Heat
Lens color	Light blue	Light blue
UV-blocking	Class II	NA
Water Content	50%±2%	48%±2%
Oxygen Permeability $x10^{-11}$ (cm^2/s)〔$mlO_2/(ml \times mmHg)$〕	91	128
Light Transmittance	95±5%	>97%
Powers	+6.00D ~ -12.25D	+20.00D ~ -20.00D
Cylinder Power	-0.25D ~ -3.50D	-0.25D ~ -10.00D
ADD Power	+0.25D ~ +3.00D	+0.50D ~ +3.00D
Refractive Index	1.405	1.400

Summary of Clinical Study

A prospective, randomized, double-blind, parallel, active-controlled clinical trial with 3 months of treatment follow-up was conducted in Taiwan. The study screened 75 subjects, 10 subjects failed to be included and 9 subjects randomized but unsuccessful lens fitting. A total of 56 subjects were enrolled in this study (39 subjects wore the test lenses and 17 subjects wore control lenses “CooperVison Biofinity® (comfilcon A) Soft Contact Lens”. A total 54 subjects completed the study, while 2 subjects in test group were discontinued from the study. The mean treatment compliance was high (98.81 % ~ 98.77 %) during the study period. Regarding the primary efficacy endpoint, the subjects with corrected contact lens visual acuity of 1.0 decimal (0.0 logMAR) or better at final visit shows no difference in control group and test group. The test and control groups are comparable in corrected contact lens visual acuity. In safety endpoints, there was no serious and significant adverse device event occurred during

the conduct of the study in both control and test group. No subject with adverse device effects accompanying Slit Lamp Findings > Grade 2 was reported in the control group and test group. Therefore, this clinical investigation supports the claim of substantial equivalence between the test product and control product with regard to clinical effectiveness and safety.

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 (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses.
Non-Clinical testing performed includes:

- Physicochemical Properties
  - Refractive Index (ISO 18369-4)
  - Oxygen Permeability (ISO 18369-4)
  - Water content (ISO 18369-4)
  - Extractable (ISO 18369-4)
  - Visible & UV Light Transmittance (ISO 18369-3)
  - Mechanical Property (ASTM D1708-13)
  - Solution Compatibility test (ISO 11981)
  - Preservative Uptake and Release (ISO 11986)
  - Shelf Life Test and Sterility Test (ISO 11987)

The results demonstrated that the lens met all established specifications and requirements for physical, optical, and chemical properties.

- Biocompatibility Test

The biocompatibility evaluation of this product was conducted in accordance with the ISO 10993 series and ISO 9394 standards for the biological evaluation of medical devices. The evaluation included relevant tests for both the contact lens materials and the packaging components:

Contact Lenses (Toufilcon B)
• Cytotoxicity Test (ISO 10993-5) • Ocular Irritation Test (ISO 10993-10) • Acute Systemic Toxicity Test (ISO 10993-11) • Skin Sensitization Study (Maximization Test) (ISO 10993-10) • 22-Day Ocular Irritation Study (ISO 9394)
PP blister and aluminum foil (identical to K232649)
• Cytotoxicity Test (ISO 10993-5) • Ocular Irritation Test (ISO 10993-10) • Acute Systemic Toxicity Test (ISO 10993-11)

Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses use the same primary packaging materials as the K232649 Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses. The raw materials and formulation of the primary packaging materials (Aluminum Foil 4-Layer and PP blister) are identical. The safety of the these materials has been verified through biocompatibility testing performed for the referenced device (K232649) in accordance with the ISO 10993 series of standards; therefore, additional testing for primary packaging was not required.

The test results demonstrated that the contact lens exhibit no cytotoxicity, no ocular irritation, no skin sensitization, and no acute systemic toxicity. All biocompatibility tests yielded passing results, confirming that the product does not contain any toxic or harmful substances that may pose a risk to biological systems.

Substantial Equivalence Statement

Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Toufilcon B) Soft (Hydrophilic) Contact Lenses are substantially equivalent to the predicate device BIOFINITY (comfilcon A) Soft Contact Lens.

All of these lenses are categorized as Group V silicone hydrogel lenses and are manufactured using the same processes: cast molding and steam sterilization. Designed for vision correction, they are available in various optical designs, including spherical/aspherical, toric, and multifocal. The Pegavision (Toufilcon B) Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision Soft (Hydrophilic)

Contact Lenses are considered substantially equivalent to the predicate device, CooperVision Biofinity® (comfilcon A) Soft Contact Lens.

Conclusion

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