September 17, 2025

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

Re: K251095
Trade/Device Name: Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 9, 2025
Received: August 14, 2025

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251095

Device Name
Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses

Indications for Use *(Describe)*
- Sphere and Asphere
Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Sphere and Asphere designs are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.
- Toric
Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Toric designs are indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters and astigmatic corrections from -0.50 to -3.50 diopters.
- Multifocal
Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Multifocal designs are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters and with nondiseased eyes who may require a reading addition from +0.25D to +3.OOD. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.
The lenses are intended for single-use disposable wear.

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.

K251095

510(k) SUMMARY

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:	August 14, 2025

Identification of Device

Trade Name:	Pegavision (Hioxifilcon A) Daily Disposable Soft 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:	K232649, Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses

Description of Device

The Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses are visibility-tinted and include UV blocker-containing materials. The lens is available in sphere, asphere, toric and multifocal designs. It is a non-ionic hydrogel lens derived from Hioxifilcon A material which is a co-polymer of 2-Hydroxyethyl methacrylate (HEMA) and 2,3-Dihydroxypropyl methacrylate (Glycerol methacrylate, GMA), cross-linked with Ethylene glycol dimethacrylate (EGDMA) and made by photo-polymerization. It consists of 41% Hioxifilcon A and 59% water by weight when immersed in buffered solution. There are two types of buffer solution, one is borate solution another one is borate solution with Tween 80, Hyaluronic Acid and Polyethylene Glycol. The lens further contains a benzotriazole UV absorbing monomer

and thus is able to block UV radiation. The lens is visibly tinted with "Reactive Blue 19", "Reactive Red 180", and "Reactive Yellow 15", which are approved color additives by the U.S. FDA and listed in 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 Hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

Table 1 details transmittance parameter of the subject device.

Table 1 Transmittance Parameter

Transmittance Property	Subject Device
Visible light @ 380~780nm	≥ 80%
UVA @ 315~380nm	< 50%
UVB@ 280~315nm	< 5%

Indications for use

Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses

- **Sphere and Asphere**

  Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Sphere and Asphere designs are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

- **Toric**

  Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Toric designs are indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters and astigmatic corrections from -0.50 to -3.50 diopters.

- **Multifocal**

  Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses with Multifocal designs are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons

with non-diseased eyes in powers from +6.00 to -12.00 diopters and with non-diseased eyes who may require a reading addition from +0.25D to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

The lenses are intended for single-use disposable wear.

Technological characteristics studies

The technological characteristics of Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses and Predicate Devices are illustrated in Table2.

Table 2 Comparison of Technological Characteristics

	Subject Device	K232649 Predicate
USAN Name	Hioxifilcon A	Hioxifilcon A
Material Classification	Group II high water non-ionic	Group II high water non-ionic
Water Content (%)	59%	59%
Refractive Index	1.400	1.400
Oxygen Permeability (edge corrected) @ 35°C	23.2×10^{-11} $(cm^2/sec)(mlO_2/ml\text{-}mmHg)$	23.2×10^{-11} $(cm^2/sec)(mlO_2/ml\text{-}mmHg)$
Transmittance Visible light @ 380~780nm	≥ 80%	≥ 80%
UV Blocker	Yes	Yes
Reduction in transmittance of light (380 nm to 450 nm)	No	Yes
Lens design	Sphere and Asphere Toric Multifocal	Sphere and Asphere Toric Multifocal

Summary of Clinical Study

Hioxifilcon A lenses have been used widely. Their safety and effectiveness have been well documented. Their safety and effectiveness can be further exemplified by K232649 cleared by FDA.

- K232649_Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses

Clinical studies for Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses of the present device are not required for the premarket notification, as the USAN name and process are the same as the predicate device.

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 (Hioxifilcon A) Daily Disposable Soft Contact Lenses.

Non-Clinical testing performed includes:

- Physicochemical Properties Test
  - Refractive Index
  - Oxygen Permeability
  - Water content
  - Extractables
  - Mechanical Property
  - Light Transmittance
  - Contact Angle Test
- Biocompatibility Test
  - Cytotoxicity Test - Contact lens, package solution, and primary package (according to ISO 10993-5)
  - Ocular Irritation Test - Contact lens, package solution, and primary package (according to ISO 10993-10 /ISO 10993-23)
  - Acute Systemic Toxicity Test - Contact lens and primary package (according to ISO 10993-11)
- Shelf Life Test and Sterility Test

Substantial Equivalence Statement

Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses (subject device) is substantially equivalent in intended use, materials (monomer, UV absorber, dye), design, safety and performance claims to the predicate device-Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses (K232649).

The subject device was visibly tined with the color additives “Reactive Yellow

15", "Reactive Blue19" and "Reactive Red 180", which are listed in 21 CFR part 73.3121.

Furthermore, successful results from chemical/physical, stability, biocompatibility tests, extractable test confirm the lenses are within established finished product specification, remain stable, and are non-toxic and biocompatible with the ocular environment.

Conclusion

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses and to establish substantial equivalence to the predicate device. Information submitted in the 510(k) also establishes that the Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses does not raise questions of safety and effectiveness.