May 31, 2023

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

Re: K222885
Trade/Device Name: Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 27, 2023
Received: April 27, 2023

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 (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 titled, "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,

J Angelo Green -S

FDA

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

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)*

K222885

Device Name
Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)

Indications for Use *(Describe)*

Sphere and Asphere

Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) with Sphere and Asphere designs are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +10.00 to -20.00 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) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) with Toric designs are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +10.00 to -20.00 diopters and astigmatic corrections from -0.50 to -6.00 diopters.

Multifocal

Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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 -12.25 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.

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

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

510(k) Number: K222885

Submitter Information

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Date Prepared:	April 27, 2023

Identification of Device

Trade Name:	Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)
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 Name:	K201268, Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) K213119, Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens

Description of Device

The Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) are clear, visibility-tinted and include UV blocker-containing. 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 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 Hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

Indications for use

Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)

- **Sphere and Asphere**

  Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) with Sphere and Asphere designs are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +10.00 to -20.00 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) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) with Toric designs are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +10.00 to -20.00 diopters and astigmatic corrections from -0.50 to -6.00 diopters.
- **Multifocal**

  Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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 -12.25 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) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) and Predicate Devices are illustrated in the following Table.

	Proposed Device	**K201268 Predicate**	**K213119 Predicate**
Production Method	Cast-Molded	Cast-Molded	Cast-Molded
USAN Name	Hioxifilcon A	Hioxifilcon A	Hioxifilcon A
Material Classification	Group II high water non-ionic	Group II high water non-ionic	Group II high water non-ionic
Water Content (%)	59%	59%	59%
Refractive Index	1.400	1.400	1.400
Oxygen Permeability (edge corrected) @ 35°C	23.2×10^{-11} $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$	20.6×10^{-11} $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$	25×10^{-11} $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$
Transmittance Visible light @ 380~780nm	> 95%	> 95%	> 95%
Transmittance UVA @ 380-315nm UVB @ 315-280nm	< 50% < 5%	< 50% < 5%	< 50% < 5%
Lens design	Sphere and Asphere Toric Multifocal	Spherie and Asphere Toric	Sphere and Asphere Toric Multifocal Multifocal Toric
Indications for Use	Indicated for daily wear for the correction of refractive ametropia in aphakic and/or non-aphakic persons with non-diseased eyes that are myopia or hyperopia and/or presbyopia and/or astigmatism.	Indicated for daily wear for the correction of refractive ametropia in aphakic and/or not-aphakic persons with non-diseased eyes that are myopia or hyperopia and/or astigmatism.	Indicated for daily wear for the correction of refractive ametropia and emmetropia in aphakic and/or non-aphakic persons with non-diseased eyes that are myopia or hyperopia and/or presbyopia and/or astigmatism.

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 three lenses cleared by FDA. The predicate devices are K201268 and K213119.

- K201268_Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)
- K213119, Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens

Clinical studies for Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) of the present device are not required for the premarket notification, as the USAN name and process are the same as the above-mentioned predicate devices.

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) One-Day Soft (Hydrophilic) Contact Lenses (59% Water).

Non-Clinical testing performed includes:

- Physicochemical Properties
  - Refractive Index
  - Oxygen Permeability
  - Water content
  - Extractables
  - Mechanical Property
  - Light Transmittance
- Biocompatibility Test
  - Cytotoxicity Test
  - Ocular Irritation Test
  - Acute Systemic Toxicity Test
- Shelf Life Test and Sterility Test

Substantial Equivalence Statement

The physical and chemical properties of Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) (Proposed Device) are similar with the commercial soft lens (K201268). It's consistent with Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) (K201268). Besides, Multifocal Deisgn is similar with Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens (K213119). The proposed device lenses are the same ingredient materials (monomer, UV absorber, dye) as predicated devices K201268 and K213119.

We've conducted manufacturing verification studies for the three alternate lens designs (Sphere/Asphere, Toric and Multifocal) to ensure that lenses meet prescribed specification with established tolerances according to the 1994 FDA Contract Lens Guidance for diameter, power, and base curve.

In conclusion, the information submitted in this premarket notification supports the substantial equivalency, the Pegavision (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water), with the same established safety profile and effectiveness as the predicate devices – Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) (K201268) and Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens (K213119).