October 15, 2020

Pegavision Corporation
Estela Lin
Regulatory Affair Senior Engineer
2F-1, No.5, Shing Yeh St.
Guishan Dist., Taoyuan City, 333 Taiwan

Re: K200296
Trade/Device Name: Pegavision (etafilcon A) Color Daily Disposable Soft (hydrophilic) Contact Lenses, Pegavision (etafilcon A) 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 8, 2020
Received: September 10, 2020

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 entitled, "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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200296

Device Name
Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*

Spherical and Aspherical

Pegavision (Etafilcon A) Color SPHERE and ASPHERE Daily Disposable Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Toric

Pegavision (Etafilcon A) Color Toric Daily Disposable Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters and astigmatic corrections from -0.25 to -3.50 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Multifocal

Pegavision (Etafilcon A) Color Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses 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 +6.50 to -12.25 diopters and with non-diseased eyes who may require a reading addition from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact 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.

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."

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K200296

Device Name
Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*

Spherical and Aspherical

Pegavision (Etafilcon A) Color SPHERE and ASPHERE Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Toric

Pegavision (Etafilcon A) Color Toric Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters and astigmatic corrections from -0.25 to -3.50 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Multifocal

Pegavision (Etafilcon A) Color Multifocal Soft (Hydrophilic) Contact Lenses 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 +6.50 to -12.25 diopters and with non-diseased eyes who may require a reading addition from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses are intended for frequent/planned replacement wear with cleaning, rinsing, disinfection 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)

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K200296

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: Mr. TS Yang, President
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Date Prepared: September 4, 2020

Identification of Device

Trade Name: Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses
Pegavision (Etafilcon A) Color Daily Disposable 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 Name: K161739 Pegavision Corporation Products
Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses, Spherical Aspherical, Toric and Multifocal

K062614 Vistakon, Division of Johnson & Johnson Vision Care Inc., VISTAKON®,(etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted(Visibility and/or Cosmetically) with UV Blocker.

K 162317 St. Shine Optical Co., Ltd., Saview-Colors Aqua 42
UV (hefilcon A) Soft (Hydrophilic) Contact Lens

Description of Device

Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are available as spherical, aspherical, toric and multifocal designs lenses. The model illuminated with high water (58 %). These hydrogel lens materials are random copolymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which were crosslinked with ethylene glycol dimethacrylate (EGDMA) and 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) via photo-polymerization. These lenses are tinted blue using C.I. reactive blue 19 to make them more visible for handling. The contact lens color additives use FDA approved colorants and combination pigmented area that will mask or enhance the apparent color of the eyes.

These lenses contain UV blocker, a benzotriazole UV absorbing monomer to block UV radiation. The average transmittance characteristics of theses lenses are less than 5% in the UVB range of 280-315 nm and less than 50% in the UVA range of 315-380nm. Lenses are supplied sterile in sealed blister package containing sterile isotonic borate buffered saline solution with Tween 80, Sodium Hyaluronate and Polyethylene Glycol.

Indications for use

1. Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses

Spherical and Aspherical

Pegavision (Etafilcon A) Color SPHERE and ASPHERE Daily Disposable Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Toric

Pegavision (Etafilcon A) Color Toric Daily Disposable Soft (Hydrophilic) Contact

Lenses 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 +6.00 to -12.00 diopters and astigmatic corrections from -0.25 to -3.50 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Multifocal

Pegavision (Etafilcon A) Color Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses 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 +6.50 to -12.25 diopters and with non-diseased eyes that may require a reading addition from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

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

2. Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses

Spherical and Aspherical

Pegavision (Etafilcon A) Color SPHERE and ASPHERE Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Toric

Pegavision (Etafilcon A) Color Toric Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.00 diopters and astigmatic corrections from -0.25 to -3.50 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Multifocal

Pegavision (Etafilcon A) Color Multifocal Soft (Hydrophilic) Contact Lenses 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 +6.50 to -12.25 diopters and with non-diseased eyes who may require a reading addition from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses are intended for frequent/planned replacement wear with cleaning, rinsing, disinfection 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.

Summary of Clinical Study

Etafilcon 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.

Clinical studies for Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses of the present device are not required for the premarket notification as the USAN name and process or color additive are the same as the above mentioned predicate devices.

Summary of Non-clinical Study

The following tests were conducted as recommended by the Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, revised May 1994.

Non-Clinical testing performed includes:

- Physicochemical Properties Test
- Biocompatibility Test
  - Cytotoxicity Test (according to ISO 10993-5)
  - Maximization Sensitization Test (according to ISO 10993-10)
  - Ocular Irritation Test (according to ISO 10993-10)
- Shelf Life Test and Sterility Test

- Extractable Test
- The Compatibility Test of Care Solution

The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and establish substantial equivalence to predicate lenses VISTAKON Contact Lens & Saview-Colors contact lens both cosmetically tinted and visibility tinted with UV blocker (K062614 and K162317) and Aquamax Soft (Hydrophilic) Contact Lenses (K161739) visibility tint with UV Blocker. The evidence of substantial equivalence to the predicate lenses is described below.

Technological characteristics studies

The technological characteristics of Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are illustrated in the following Table.

Item	**Proposed Device**	K161739 **Predicate**	K062614**Predicate**	K162317**Predicate**
Production Method	Cast-Molded	Cast-Molded	Cast-Molded	Cast-Molded
USAN Name	Etafilcon A	Etafilcon A	Etafilcon A	hefilcon A
Material Classification	Group 4 high water ionic	Group 4 high water ionic	Group 4 high water ionic	Group 1 low water non-ionic
Water Content (%)	58%	58%	58%	42%
Refractive Index	1.402	1.402	1.40	1.4347
Oxygen Permeability (edge corrected) @ 35°C	19.73 x 10^{-11} (cm^2/sec)(ml O_2/ml-mmHg)	19.73 x 10^{-11} (cm^2/sec)(ml O_2/ml-mmHg)	28 x 10^{-11} (cm^2/sec)(ml O_2/ml-mmHg)	10.89x 10^{-11} (cm^2/sec)(ml O_2/ml-mmHg)
Light Transmittance **UVA Transmittance** **UVB Transmittance**	> 95% < 50% < 5%	> 95% < 50% < 5%	> 85% < 50% < 5%	> 95% < 10% < 1%
Lens design	Spherical Aspherical Toric Multifocal	Spherical Aspherical Toric Multifocal	Spherical Bifocal Toric Bifocal-Toric	Spherical Toric Multifocal
Indications for Use	Indicated for daily wear for the correction of refractive ametropia in aphakic and/or non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia and/or astigmatism.	Indicated for daily wear for the correction of refractive ametropia in aphakic and/or non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia and/or astigmatism.	Indicated for daily wear for the correction of visual acuity / refractive ametropia / distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes.	Myopia, hyperopia, presbyopia and astigmatism
Packaging	PP Blister Pack	PP Blister Pack	PP Blister Pack	PP Blister Pack
Packaging solution	Borate buffered saline (with Tween 80, Sodium hyaluronate and Polyethylene Glycol)	Borate buffered saline (with Tween 80, Sodium hyaluronate and Polyethylene Glycol)	buffered saline	Saline solution containing hyaluronic acid polymer

Substantial Equivalence Statement

Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses for daily wear that are the subject of this 510(k) submission are equivalent to the predicate devices. Successful results from chemical/physical, stability, biocompatibility tests, extractable test and care solution compatibility 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 (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and to establish substantial equivalence to the predicate devices. Information submitted in the 510(k) also establishes that the Pegavision Color Soft Contact Lenses do not raise questions of safety and effectiveness. Therefore, Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are substantially equivalent to the predicate devices.