December 6, 2021

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

Re: K211448
Trade/Device Name Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses,
Aquamax (Etafilcon A) 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: October 28, 2021
Received: November 2, 2021

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, 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)*
K211448

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

Indications for Use *(Describe)*

Spherical and Aspherical

Aquamax (Etafilcon A) 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.

Toric

Aquamax (Etafilcon A) 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 -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters.

Multifocal

Aquamax (Etafilcon A) 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 +6.00 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 2.00 diopters or less that does not interfere with visual acuity.

Aquamax (Etafilcon A) 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.

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)*
K211448

Device Name
Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*

Spherical and Aspherical

Aquamax (Etafilcon A) 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.

Toric

Aquamax (Etafilcon A) 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 -12.25diopters and astigmatic corrections from -0.25 to -3.50 diopters.

Multifocal

Aquamax (Etafilcon A) 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 +6.00 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 2.00 diopters or less that does not interfere with visual acuity.

The 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K211448

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
Phone:	886-3-329-8808
Fax:	886-3-329-8897
E-Mail:	TSYang@pegavision.com
Date Prepared:	December 01, 2021

Identification of the Predicate Device

Trade Name:	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses Aquamax (Etafilcon A) 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:	**K200296 Pegavision Products** Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses

Description of Device

The Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses are clear, visibility-tinted, UV absorber-containing and are available in spherical, aspherical, toric and multifocal designs. It is an ionic hydrogel lens derived from Etafilcon A material which is a co-polymer of 2-Hydroxyethyl Methacrylate (HEMA) and Methacrylic Acid (MAA), cross-linked with Ethylene Glycol Dimethacrylate (EGDMA) and 1,1,1-Trimethylolpropane Trimethacrylate (TMPTMA) and made by photo-polymerization. The lens consists of 42% Etafilcon A and 58% water by weight when immersed in buffered saline solution. The lens polymer further contains benzotriazole, a UV absorbing monomer, thus is able to block the UV radiation to the ocular. . 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. The lens is visibly tined with ”Reactive Blue19” color additive, 21 CFR section 73.3121. Lenses are supplied sterile in the sealed blister package containing sterile isotonic borate buffered saline solution with Tween 80, Sodium Hyaluronate, Polyethylene Glycol, and Cyanocobalamin as a color indicator to induce the package solution as pink color.

Indications for use

1. Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses Spherical and Aspherical

Aquamax (Etafilcon A) 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.

Toric

Aquamax (Etafilcon A) 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 -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters.

Multifocal

Aquamax (Etafilcon A) 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 +6.00 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 2.00 diopters or less that does not interfere with visual acuity.

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

2. Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses

Spherical and Aspherical

Aquamax (Etafilcon A) 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.

Toric

Aquamax (Etafilcon A) 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 -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters.

Multifocal

Aquamax (Etafilcon A) 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 +6.00 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 2.00 diopters or less that does not interfere with visual acuity.

The 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 the lenses cleared by FDA.

Clinical studies for Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses 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.

Summary of Non-clinical Study

a) Non-Clinical Testing performed

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

Includes:

- Physicochemical Properties Test
- Biocompatibility Test

Contact Lenses (Etafilcon A)
• Cytotoxicity Test (according to ISO 10993-5) • Maximization Sensitization Test (according to ISO 10993-10) • Ocular Irritation Test (according to ISO 10993-10) • Acute Systemic Toxicity Test (according to ISO 10993-11)
Packaging Solution
• Cytotoxicity Test (according to ISO 10993-5) • Ocular Irritation Test (according to ISO 10993-10)
Plastic Container (Foil& PP Blister)
• Cytotoxicity Test (according to ISO 10993-5) • Ocular Irritation Test (according to ISO 10993-10) • Acute Systemic toxicity test (according to ISO 10993-11)

- Extractable Test
- Shelf Life Test and Sterility Test

The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and establish substantial equivalence to predicate lenses Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses (K200296). The evidence of substantial equivalence to the predicate lenses is described below.

b) Technological characteristics studies

The technological characteristics of Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses are illustrated in the following Table.

	Proposed Device	**K200296 Predicate**
Production Method	Cast-Molded	Cast-Molded
USAN Name	Etafilcon A	Etafilcon A
Material Classification	Group IV high water ionic	Group IV high water ionic
Water Content (%)	58%	58%
Refractive Index	1.402	1.402
Oxygen Permeability (edge corrected) @ 35°C	19.73×10^{-11} $(cm^2/sec)(mlO_2/ml\text{-}mmHg)$	19.73×10^{-11} $(cm^2/sec)(mlO_2/ml\text{-}mmHg)$
Transmittance **Visible light @ 380~780nm** **UVA @ 380-315nm** **UVB @ 315-280nm**	 > 95% < 50% < 5%	 > 95% < 50% < 5%
Lens design	Spherical and Aspherical Toric Multifocal	Spherical and Aspherical Toric Multifocal
Packaging solution	Borate buffered saline (with Tween 80, Sodium hyaluronate, Polyethylene Glycol, and Cyanocobalamin)	Borate buffered saline (with Tween 80, Sodium hyaluronate, Polyethylene Glycol)

Substantial Equivalence Statement

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses for daily wear submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the predicate devices - Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses, Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses (K200296). 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. Differences between the devices are the package solution, which cited in this section do not raise any new issues of substantial equivalence.

Conclusion

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and to establish substantial equivalence to the predicate devices. Information submitted in the 510(k) also establishes that the Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses do not raise questions of safety and effectiveness. Therefore, Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses are substantially equivalent to the predicate devices - Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses, Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses (K200296).