February 2, 2022

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

Re: K211603
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: December 23, 2021
Received: December 27, 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)*
K211603

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

Indications for Use *(Describe)*

Sphere and Asphere

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses 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 +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) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters.

Multifocal

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) 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 -12.25 diopters and with non-diseased eyes who may require a reading addition form +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.

Multifocal-Toric

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses with Multifocal-Toric 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 -12.25 diopters who may need up to +3.00 diopters of ADD power and have -3.50 diopters of astigmatism or less.

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

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*"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."*

# 510(k) SUMMARY

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

## Submitter Information

| | |
|---|---|
| Company: | PEGAVISION CORPORATION<br>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: | January 28, 2022 |

## Identification of Device

| | |
|---|---|
| Trade Name: | Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses<br>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<br>Lens. Soft Contact (Disposable). 21CFR. 886.5925, Product Code MVN |
| FDA Classification: | Class II |
| Predicate Device Name: | K200296, Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses, Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses<br>K141670, ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV (ultraviolet) Blocker for Daily Wear |

## 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 sphere, asphere, toric, multifocal and multifocal-toric designs. It is an ionic hydrogel lens derived from Etafilcon A material which is a co-polymer of 2-Hydroxyethyl Methacrylate (2-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 a 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 part 73.3121. Lenses are supplied sterile in the sealed blister package containing sterile isotonic borate buffered saline solution with Tween 80, Sodium Hyaluronate and Polyethylene Glycol.

## Indications for use

**Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses**

**Sphere and Asphere**

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses 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 +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) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses 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 +6.00 to -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters.

**Multifocal**

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) 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 -12.25 diopters and with non-diseased eyes who may require a reading addition form +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.

**Multifocal-Toric**

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses with Multifocal-Toric 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 -12.25 diopters who may need up to +3.00 diopters of ADD power and have -3.50 diopters of astigmatism or less.

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

## 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 two lenses cleared by FDA.

- Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses, K200296 Submitted by Pegavision Corporation, Taiwan.
- ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV (ultraviolet) Blocker for Daily Wear, K141670 Submitted by Johnson & Johnson Vision Care, Inc.

Clinical studies for Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and 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)<br>• Ocular Irritation Test (according to ISO 10993-10)<br>• Acute Systemic Toxicity Test (according to ISO 10993-11) |
| Packaging Solution |
| • Cytotoxicity Test (according to ISO 10993-5)<br>• Ocular Irritation Test (according to ISO 10993-10) |
| Plastic Container (Foil& PP Blister) |
| • Cytotoxicity Test (according to ISO 10993-5)<br>• Ocular Irritation Test (according to ISO 10993-10)<br>• 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) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses, which have the same lens materials, packaging solution, and manufacturing process with predicate lenses Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses (K200296). In addition, the Multifocal and Multifocal-Toric lens designs are the same with predicate lenses ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear (K141670).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** | **K141670 Predicate** |
|---|---|---|---|
| **Production Method** | Cast-Molded | Cast-Molded | Cast-Molded |
| **Lens Designs** | Sphere and Asphere, Toric, Multifocal, Multifocal-Toric | Sphere and Asphere, Toric, Multifocal | Multifocal, Multifocal-Toric |
| **USAN Name** | Etafilcon A | Etafilcon A | Etafilcon A |
| **Material Classification** | Group IV high water ionic | Group IV high water ionic | Group IV high water ionic |
| **Water Content (%)** | 58% | 58% | 58% |
| **Refractive Index** | 1.402 | 1.402 | 1.402 |
| **Oxygen Permeability (edge corrected) @ 35°C** | $19.73 \times 10^{-11}$ $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$ | $19.73 \times 10^{-11}$ $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$ | $21.4 \times 10^{-11}$ $(cm^2/sec)(ml O_2/ml\text{-}mmHg)$ |
| **Cosmetically tinted** | N/A | To enhance or alter the appearance of the eye | To enhance or alter the appearance of the eye |
| **Percent Transmittance**<br>**% T at 380~780nm**<br>**% T at 315-380nm**<br>**% T at 280-315nm** | > 95%<br>< 50%<br>< 5% | > 95%<br>< 50%<br>< 5% | > 95%<br>< 30%<br>< 5% |
| **Packaging Solution** | Saline A: Borate buffered saline<br>Saline B: Borate buffered saline (with Tween 80, Sodium Hyaluronate, and Polyethylene Glycol) | Borate buffered saline (with Tween 80, Sodium hyaluronate, Polyethylene Glycol) | Borate buffered saline |

## Substantial Equivalence Statement

Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the predicate devices (K200296 & K141670).

Successful results from the 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 Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses. Information submitted in the 510(k) establishes that the proposed devices have the same materials and manufacture process with the predicate devices - Pegavision (Etafilcon A) Color Soft (Hydrophilic) Contact Lenses and Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses (K200296), and the same lens designs of Multifocal and Multifocal-Toric with the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV (ultraviolet) Blocker for Daily Wear (K141670). Therefore, 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, and substantial equivalence to the predicate devices.