DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 19, 2016

Pegavision Corporation
Mr. Tony Hsu
President
2F-1, No.5, Shing Yeh St.
Guishan Dist
Taoyuan City 333
Taiwan

Re: K161739
Trade/Device Name: Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses
Aquamax (Etafilcon A) Daily Disposable 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: November 1, 2016
Received: November 14, 2016

Dear Mr. Hsu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161739

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

Indications for Use *(Describe)*

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 +20.00 to -20.00 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 -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 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 -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up 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 help protect against transmission of harmful UV radiation to the cornea and into the eye. The 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 +20.00 to -20.00 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 -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 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 -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up 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) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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)

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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. Tony Hsu, President
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Date Prepared:	June 03, 2016

Identification of Device

Trade Name:	Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses Aquamax (Etafilcon A) 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:	K120028 Pegavision Corporation, Aquamax (Etafilcon A) disposable soft (hydrophilic) contact lenses K962804 Vistakon, Johnson & Johnson Vision Products, ACUVUE (Etafilcon A) Spherical, Toric, and Multifocal, and Toric Multifocal soft (hydrophilic) daily wear contact lenses K 991134 Vistakon, Johnson & Johnson Vision Products, ACUVUE (Etafilcon A) spherical, bifocal, toric and toric bifocal soft (hydrophilic) daily wear contact lenses, clear and visibility tint with UV blocker

Description of Device

Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are available as spherical, aspherical, toric and multifocal 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. 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 316-380nm. 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. **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 +20.00 to -20.00 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 -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 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 -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up 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 help protect against transmission of harmful UV radiation to the cornea and into the eye. The 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 +20.00 to -20.00 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 -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 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 -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up 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) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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 three lenses cleared by FDA.

- ACUVUE (Etafilcona A) Contact lens, clear and visibility tint with UV blocker, K 962804 Submitted by Vistakon USA
- ACUVUE (Etafilcon A) Contact lens, clear and visibility tint with UV blocker, K 991134 Submitted by Vistakon USA
- Aquamax (EtafilconA) Disposable Soft (Hydrophilic) Contact Lenses, K120028 Submitted by Pegavision Corporation, Taiwan

Clinical studies for Aquamx (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.

Non-clinical Study

All tests were conducted in accordance with the May 1994 FDA guideline title Premarket Notification 510(K) Guidance Document for Class IV Contact Lenses.

The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and establish substantial equivalence to predicate lenses ACUVUE Contact Lens clear and visibility tint with UV blocker (K962804 & K991134) and Aquamax Disposable Soft (Hydrophilic) Contact Lenses (K120028) visibility tint with UV Blocker. The evidence of substantial equivalence to the predicate lenses is described below.

a) Technological characteristics studies

The technological characteristics of Aquamax (Etafilcon A) Soft (Hydrophilic)

Contact Lenses are illustrated in the following Table.

	Proposed Device	**K120028 Predicate**	**K962804 Predicate**	**K991134 Predicate**
Production Method	Cast-Molded	Cast-Molded	Cast-Molded	Cast-Molded
USAN Name	Etafilcon A	Etafilcon A	Etafilcon A	Etafilcon A
Material Classification	Group 4 high water ionic	Group 4 high water ionic	Group 4 high water ionic	Group 4 high water ionic
Water Content (%)	58%	58%	58%	58%
Refractive Index	1.402	1.402	1.40	1.40
Oxygen Permeability (edge corrected) @ 35℃	19.73×10^{-11} $(cm^2/sec)(ml\ O_2/ml\text{-}mmHg)$	19.73×10^{-11} $(cm^2/sec)(ml\ O_2/ml\text{-}mmHg)$	26×10^{-11} $(cm^2/sec)(ml\ O_2/ml\text{-}mmHg)$	26.3×10^{-11} $(cm^2/sec)(ml\ O_2/ml\text{-}mmHg)$
Percent Transmittance				
% T at 593nm	> 95%	> 95%	> 85%	> 85%
% T at 380-315nm	< 50%	< 50%	< 30%	< 30%
% T at 315-280nm	< 5%	< 5%	< 5%	< 5%
Lens design	Spherical Aspherical Toric Multifocal	Spherical Aspherical	Spherical Toric Multifocal Toric Multifocal	Spherical Bifocal Toric Toric bifocal
Packaging solution	Borate buffered saline (with Tween 80, Sodium hyaluronate and Polyethylene Glycol)	Borate buffered saline	N/A	N/A

b) Biocompatibility

The standard cytotoxicity, maximization sensitization and ocular irritation tests were carried out for both Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and negative responses were recorded for all tests. The validity of blister package for lenses was demonstrated by passing the standard extraction tests.

c) Microbiology

Steam sterilization process had been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA group IV. There is shelf-life stability supporting that these lenses remain sterile through the expiration date claimed for the product

d) Bacteriostatic Validation

The steam sterilizer was tested for effectiveness by measuring and demonstrating the uniformity of temperature at different location inside the sterilizer over test period. Tested microorganisms were killed under tested conditions as compared to control.

Lenses remained sterilized and there was no microbial growth for a period of 5 years tested under accelerated condition. Seal of lens packages remained tight for a period of 5 years as demonstrated by the constant peeling strength tested under accelerated condition.

e) Leachability

Studies were conducted to determine the leachable materials from the finished lenses. The results show that, at the levels of the detection reported, there are no leachable monomers and additive residues.

Substantial Equivalence Statement

The pH and Osmolality of Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses(Proposed Device) are within the normal range of packaging solution for commercial soft lens. It's consistent with our previously approved Aquamax (Etafilcon A) lenses (K120028).

In addition, we've conducted manufacturing verification studies for the two alternate lens designs (toric and spherical 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, it is PEGAVISION's conviction that data submitted in this 510(K) to validate the claim of substantial equivalency, substantiates our ability to manufacture soft contact lenses, the Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, with the same established safety profile and effectiveness as the predicate devices – Aquamax Disposable Soft (Hydrophilic) Contact Lenses and, the ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker cleared via K962804 and K991134.