



October 21, 2020

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

Re: K201268

Trade/Device Name: Ethos Aquell (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: September 15, 2020

Received: September 18, 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, 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

Indications for Use

510(k) Number (if known)

K201268

Device Name

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

Indications for Use (Describe)

Spherical and Aspheric

Ethos Aquell (Hioxifilcon A) Spherical and Aspheric One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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

Ethos Aquell (Hioxifilcon A) Toric One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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.

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.

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510(k) SUMMARY

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

Establishment Information

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Application Correspondent

Company: PEGAVISION CORPORATION
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Email: EstelaLin@pegavision.com

Date Prepared: April 09, 2020

Identification of Device

Trade Name: Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic)
Contact Lenses (59% Water)

Common Name: Soft (hydrophilic) Contact Lenses (daily wear)
Lenses, Soft Contact, Daily Wear 21CFR. 886.5925, Product
Code LPL

Classification Name: Lens. Soft Contact (Disposable). 21CFR. 886.5925,
Product Code MVN

FDA Classification: Class II
K040303 Hydrogel Vision Corporation

Predicate Device Name: 59% Extreme H2O (hioxifilcon A) Soft Contact Lens for
Daily Wear (cast-molded, with a visibility tint)

Description of Device

The Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) are clear, visibility-tinted and include UV blocker-containing. The lens is available in spherical, aspherical and toric designs. It is a non-ionic hydrogel lens derived from Hioxifilcon A material which is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (GlycerolMethacrylate, 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 (Saline 2); another one is borate solution with sodium hyaluronate (Saline 1). The lens polymer further contains a benzotriazole UV absorbing monomer and thus is able to block UV radiation. The lens is visibly tinted with "Reactive Blue19" color additive, 21 CFR part 73.3121.

Indications for use

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

Spherical and Aspheric

Ethos Aquell (Hioxifilcon A) Spherical and Aspheric One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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

Ethos Aquell (Hioxifilcon A) Toric One-Day Soft (Hydrophilic) Contact Lenses (59% Water) 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.

The lenses are intended for single-use disposable wear.

Technological characteristics studies

The technological characteristics of Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) and Predicate Device (K040303) are illustrated in the following Table.

	Proposed Device	K040303 Predicate
Production Method	Cast-Molded	Cast-Molded
USAN Name	Hioxifilcon A	Hioxifilcon A
Material Classification	Group 2 high water non-ionic	Group 2 high water non-ionic
Water Content (%)	59%	59%
Refractive Index	1.400	1.404
Oxygen Permeability (edge corrected) @ 35°C	20.6 x 10 ⁻¹¹ (cm ² /sec)(mlO ₂ /ml-mmHg)	18 x 10 ⁻¹¹ (cm ² /sec)(mlO ₂ /ml-mmHg)
Transmittance Visible light @ 380~780nm	> 95%	> 95%
Transmittance UVA @ 380-315nm UVB @ 315-280nm	< 50% < 5%	N/A N/A
Lens design	Spherical and Aspheric Toric	Spherical 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 astigmatism.	Indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopia or hyperopia 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.

- 59% Extreme H₂O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint)
K040303 Submitted by Hydrogel Vision Corporation
- 59% Extreme H₂O (hioxifilcon A) Soft Contact Lens
K992692 Submitted by Benz Research and Development
- BENZ-G 5X (hioxifilcon A) Soft (Spherical) Daily Wear Contact Lens
K983773 Submitted by Benz Research and Development

Clinical studies for Ethos Aquell (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 Ethos Aquell (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 Testing
 - Contact Lens: 59% Hioxifilcon A Soft Contact Lens [Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water)]
 - 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)
 - Package Solution: Saline 1
 - Cytotoxicity Test (according to ISO 10993-5)
 - Ocular Irritation Test (according to ISO 10993-10)
 - Primary Packaging: Foil and 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)
- Shelf Life Test and Sterility Test

Substantial Equivalence Statement

The physical and chemical properties of Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water) (Proposed Device) are similar with the commercial soft lens (K040303). It's consistent with 59% Extreme H₂O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint) (K040303).

In addition, Ethos Aquell lens contains a UV absorber which is the same as that used in Aquamax (K161739). Ethos Aquell lenses were manufactured by the same photo curing process as that of Aquamax (K161739).

We've conducted manufacturing verification studies for the two alternate lens designs (Spherical/Aspheric and Toric) 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 Ethos Aquell (Hioxifilcon A) One-Day Soft (Hydrophilic) Contact Lenses (59% Water), with the same established safety profile and effectiveness as the predicate devices – 59% Extreme H₂O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint) (K040303).