



Food and Drug Administration
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August 26, 2016

Vision Science Co., Ltd.
% Mr. Bret Andre
Consultant/Official Correspondent
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Re: K161124

Trade/Device Name: EYEREVE (hioxifilcon D) Soft (hydrophilic)
Contact Lens for Daily Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: July 13, 2016

Received: July 18, 2016

Dear Mr. Andre:

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 yours,


Kesia Alexander

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
Enclosure

Indications for Use

510(k) Number (if known)

Device Name

EYEREVE (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use (Describe)

The EYEREVE (hioxifilcon D) Spherical Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The EYEREVE (hioxifilcon D) Toric Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for single use daily disposable wear. When Prescribed for daily disposable wear the lens is to be discarded after each removal.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K161124**

Applicant information:

Date Prepared: April 15th, 2016

Name: **VISION SCIENCE CO., LTD.**
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 Gyeongsan-si, Gyeongsangbuk-do,
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Consultant: Bret J Andre
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 6119 Canter Ln
 West Linn, OR 97068
 United States
 (503) 372-5226

Device Information:

Device Classification: Class II

Classification Number: LPL; MVN

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Trade Name: **EYEREVE (hioxifilcon D) Soft (hydrophilic) Contact Lens
for Daily Wear**

Predicate Devices:

The **EYEREVE (hioxifilcon D) Soft Contact Lenses** are substantially equivalent to the following predicate device(s):

“Extreme H₂O 54% (hioxifilcon D) Soft Contact Lens”

Hydrogel Vision Corporation
510(k) number; **K051430**

“Clalen 54 (Hioxifilcon D) Soft Contact Lens”

Interojo Inc.
510(k) number; **K153766**

“ISENS (polymacon)” ~ Reference Predicate

Vision Science Co., Ltd.
510(k) number; **K132714**

“55 UV (methafilcon A)” ~ Reference Predicate

Optical Connection Inc.
510(k) number; **K051095**

Device Description:

The EYEREVE Soft Contact Lenses are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material (hioxifilcon D) is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and 2,3- Dihydroxypropyl Methacrylate (Glycerol Methacrylate), cross-linked with ethylene glycol dimethacrylate (EGDMA). The co-polymer consists of 46% hioxifilcon D and 54% water by weight when immersed in saline solution. The hioxifilcon D name has been adopted by the United States Adopted Names Council (USAN).

A UV absorbing monomer—2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl]ethyl methacrylate—is incorporated in the EYEREVE contact lens material to block UV radiation. The UV blocking characteristics of the lens are as follows:

- >95% in the UVB range of 280nm - 315nm
- >67% in the UVA range of 316nm - 380nm.

EYEREVE Soft Contact Lenses are available clear or tinted to enhance or alter the apparent color of the eye. Lenses are tinted with one or a combination of one or more of the following ‘listed’ color additives:

Name of Colorant	Listing
Titanium Dioxide	21 CFR § 73.3126
Phthalocyanine Green	21 CFR § 73.3124
Carbazole Violet	21 CFR § 73.3107
Reactive Blue 19	21 CFR § 73.3127
C.I. Reactive black 5	21 CFR § 73.3127

Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the tinted lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed reactive color additive in the center of the contact lens (between layers of contact lens material) in a location that corresponds to the iris. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens. The tinting pattern has a standard Clear Pupil diameter of 6.0 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (hioxifilcon D) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 54% water by weight. The physical properties of the lens are:

Refractive Index	1.40 (hydrated)
Light Transmission	greater than 98%
Light Transmission (tinted)	greater than 96% (at region corresponding to pupil); Opaque or 0-10% (at region corresponding to iris)
Water Content	54 % ± 2%
Oxygen Permeability	21.50×10^{-11} (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C)

The EYEREVE soft contact lenses will be manufactured in the sphere and toric design configurations with the following features and properties:

Chord Diameter:	12.80 mm to 15.00 mm
Center Thickness:	0.050 mm to 0.210 mm
Base Curve:	8.0 mm to 9.8 mm
Power Range	
- Sphere Power:	-20.00D to +20.00D in 0.25D steps
- Cylinder Power (toric):	-0.25D to -4.00D in 0.25D steps
- Cylinder Axis (toric):	10° to 180° in 10° steps

Indications for Use:

The **EYEREVE (hioxifilcon D) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **EYEREVE (hioxifilcon D) Toric** Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eye care practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eye care practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When Prescribed for daily disposable wear the lens is to be discarded after each removal.

Pre-Clinical Performance:

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the EYEREVE (hioxifilcon D) finished contact lenses. The results support the claim that the EYEREVE (hioxifilcon D) Soft Contact Lenses are substantially equivalent to the currently marketed predicate devices. A summary of the results from the preclinical studies is presented below.

Toxicology:

All non-clinical toxicology tests were conducted in accordance with the GLP regulation.

In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that the test article is non-toxic.

Systemic Toxicity: The lens material meets the requirements of the systemic injection test in accordance with ISO 10993-11 and is considered non-toxic.

Acute Ocular Irritation: Acute ocular irritation test was performed in accordance with ISO 10993-10 and produced no ocular irritation.

Shelf Life

The data presented supports substantial equivalence of the EYEREVE (hioxifilcon D) finished contact lenses to the already marketed predicate devices.

Physicochemical & Mechanical Properties

The following tests were completed to verify substantial equivalence: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the EYEREVE (hioxifilcon D) contact lenses and the predicate devices.

Substantial Equivalence:

The EYEREVE (hioxifilcon D) soft contact lenses will be manufactured according to specified process controls and a cGMP quality assurance program currently in place as established by the ISENS reference predicate device (K132714).

The final packaging and sterilization of the EYEREVE (hioxifilcon D) soft contact lenses will be carried out in accordance with procedures specified for the ISENS reference predicate device (K132714).

The EYEREVE (hioxifilcon D) soft contact lenses are substantially equivalent to the predicate device as depicted in the following table, and do not raise different questions of safety and effectiveness than the predicate device identified previously.

The following table depicts the pre-clinical characteristics of the EYEREVE (hioxifilcon D) materials, as well as the predicate devices.

Substantial Equivalence Matrix

	Vision Science Co., Ltd. EYEREVE (Subject Device)	Hydrogel Vision Corp. Extreme H2O 54% (Predicate Device)	Interjo Inc. Clalen 54 (Predicate Device)	Vision Science Co., Ltd. ISENS (Predicate Device)	Optical Connection UV 55 (Predicate Device)
Intended Use	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Indications	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)				
Production Method	Fully molded				
USAN name	hioxifilcon D	hioxifilcon D	hioxifilcon D	polymacon	methafilcon A
Water Content (%)	54±2%	54±2%	54±2%	38±2%	55±2%
Oxygen Permeability	21.50×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	14.86×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	18.42×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	12.48×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	18.90×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)
FDA Group	FDA Group 2 (>50% H ₂ O, non-ionic polymer)	FDA Group 2 (>50% H ₂ O, non-ionic polymer)	FDA Group 2 (>50% H ₂ O, non-ionic polymer)	FDA Group 1 (<50% H ₂ O, non-ionic polymer)	FDA Group 2 (>50% H ₂ O, non-ionic polymer)
Refractive Index (hydrated)	1.40	1.41	1.40	1.43	1.41
UV Blocker	Yes	No	Yes	No	Yes