DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2016

Interojo, Inc.
% Mr. Bret Andre
Official Correspondent
Eyereg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Re: K153766
Trade/Device Name: Clalen 54 (hioxifilcon D) Soft (hydrophilic) Contact Lens For Daily Wear
Clalen 58 (hioxifilcon A) 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: March 3, 2016
Received: March 4, 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,

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

Enclosure

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)*
K153766

Device Name
Clalen 54 (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The Clalen 54 (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 for visibility and handling.

The Clalen 54 (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 for visibility and handling.

The Clalen 54 (hioxifilcon D) Multifocal 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 presbyopic persons requiring an add power ranging from +1.25D to +2.50D, and 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 for visibility and handling.

The Clalen 54 (hioxifilcon D) Toric-Multifocal 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, possesses refractive astigmatism not exceeding 5.00 diopters. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D. The lens is available clear or tinted for visibility and handling.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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)*
K153766

Device Name
Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The Clalen 58 (hioxifilcon A) 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 for visibility and handling.

The Clalen 58 (hioxifilcon A) 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 for visibility and handling.

The Clalen 58 (hioxifilcon A) Multifocal 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 presbyopic persons requiring an add power ranging from +1.25D to +2.50D, and 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 for visibility and handling.

The Clalen 58 (hioxifilcon A)) Toric-Multifocal 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, possesses refractive astigmatism not exceeding 5.00 diopters. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D. The lens is available clear or tinted for visibility and handling.

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)

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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: K153766

Applicant information:

Date Prepared:	December 28th, 2015
Name: Address	**Interojo, Inc.** 28& 25 Sandan-Ro 15 Beon-Gil Pyongtaek-City, Gyeonggido 459040 South Korea
Contact Person:	Si-Chul Rho President
Phone number:	+82-2-780-1225
Correspondent:	Bret J Andre EyeReg Consulting, Inc. 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:	**Clalen 54 (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear** **Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear**

Equivalent Devices:

The **Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) Soft Contact Lenses** are substantially equivalent to the following predicate device(s):

Predicate device:

"**Extreme H_2O 59% (hioxifilcon A) Soft Contact Lens**"
Manufactured/distributed by Hydrogel Vision Corporation.
510(k) number; **K992692**

"**Extreme H_2O 54% (hioxifilcon D) Soft Contact Lens**"
Manufactured/distributed by Hydrogel Vision Corporation.
510(k) number; **K051430**

"I-55 (methafilcon A)"
Manufactured by Interojo, Inc.
Distributed by PolyVue Distribution, Inc.
510(k) number; **K080794**
~ Reference Predicate

"EZvue UV (ocufilcon D)"
Manufactured by I-SEE VISION TECHNOLOGY INC.
510(k) number; **K150293**
~ Reference Predicate

Clalen 54 (hioxifilcon D) Device Description:

The Clalen 54 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 lens is available with a blue visibility-handling tint, which includes [phthalocyaninato (2-)] copper and Reactive Blue 69. The hioxifilcon D name has been adopted by the U.S. Adopted Names Council (USAN).

A UV absorbing monomer—2-(Benzoyl-3-hydroxyphenoxy)ethyl acrylate—is incorporated in the Clalen 58 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
- >70% in the UVA range of 316nm - 380nm.

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	1.404 (hydrated)
Light Transmission	greater than 96%
Water Content	54 % ± 2%
Oxygen Permeability	18.42 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35^{o}C)

Clalen 58 (hioxifilcon A) Device Description:

The Clalen 58 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 A) 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 41% hioxifilcon A and 59% water by weight when immersed in saline solution. The lens is available with a blue visibility-handling tint, which includes Reactive Blue 69. The hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

A UV absorbing monomer—2-(Benzoyl-3-hydroxyphenoxy)ethyl acrylate—is incorporated in the Clalen 58 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
- >85% in the UVA range of 316nm - 380nm.

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 A) 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 59% water by weight. The physical properties of the lens are:

Refractive Index	1.403 (hydrated)
Light Transmission	greater than 98%
Water Content	59% ± 2%
Oxygen Permeability	20.76 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35^{o}C), (revised Fatt method).

Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) Specifications:

The Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) soft contact lenses will be manufactured in the sphere, toric, multifocal, and toric multifocal design configurations with the following features and properties:

Chord Diameter:	13.00 mm to 15.00 mm
Center Thickness:	0.080 mm to 0.580 mm
Base Curve:	8.0 mm to 9.8 mm
Power Range	
- Sphere Power:	-12.00D to +12.00D in 0.25D steps
- Cylinder Power (toric):	-0.25D to -2.25D in 0.25D steps
- Cylinder Axis (toric):	10° to 180° in 10° steps
- Multifocal Power:	+1.25 to +2.50 in 0.25D steps

Indications for Use:

The **Clalen 54 (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 for visibility and handling.

The **Clalen 54 (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 for visibility and handling.

The **Clalen 54 (hioxifilcon D) Multifocal** 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 presbyopic persons requiring an add power ranging from +1.25D to +2.50D, and 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 for visibility and handling.

The **Clalen 54 (hioxifilcon D) Toric-Multifocal** 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, possesses refractive astigmatism not exceeding 5.00 diopters. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D. The lens is available clear or tinted for visibility and handling.

The **Clalen 58 (hioxifilcon A) 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 for visibility and handling.

The **Clalen 58 (hioxifilcon A) 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 for visibility and handling.

The **Clalen 58 (hioxifilcon A) Multifocal** 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 presbyopic persons requiring an add power ranging from +1.25D to +2.50D, and 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 for visibility and handling.

The **Clalen 58 (hioxifilcon A)) Toric-Multifocal** 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, possesses refractive astigmatism not exceeding 5.00 diopters. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D. The lens is available clear or tinted for visibility and handling.

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.

Pre-Clinical Performance:

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) finished contact lenses. The results support the claim that the Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) Soft Contact Lenses are substantially equivalent to the currently marketed Hydrogel Vision Corporation hioxifilcon D (K051430) & hioxifilcon A (K992692) contact lenses. 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: The test article meets the requirements of the Agarose Overlay Method in accordance with ISO 10993-5.

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 Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) finished contact lenses to the already marketed Hydrogel Vision Corporation hioxifilcon D (K051430) & hioxifilcon A (K992692) contact lenses, the predicate devices.

Physicochemical & Mechanical Properties

Results of physicochemical and mechanical property testing demonstrate consistent material properties between the Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) contact lenses and the predicate devices.

Manufacturing/Design Verification

Results of manufacturing/design verification studies demonstrate the ability of Interojo, Inc. to manufacture, on a repeatable basis, the Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) soft contact lens to a desired and predictable result within engineering tolerance and lens specifications.

Substantial Equivalence:

The Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) soft contact lenses will be manufactured according to specified process controls and a cGMP quality assurance program currently in place as established by the I-55 reference predicate device (K080794).

The final packaging and sterilization of the Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) soft contact lenses will be carried out in accordance with procedures specified for the I-55 reference predicate device (K080794).

The Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) 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 Clalen 54 (hioxifilcon D) & Clalen 58 (hioxifilcon A) materials, as well as the predicate devices.

Substantial Equivalence Matrix

	Interojo, Inc. Clalen 54 (Subject Device)	**Interojo, Inc. Clalen 58 (Subject Device)**	**Hydrogel Vision Corp. Extreme H2O 54% (Predicate Device)**	**Hydrogel Vision Corp. Extreme H2O 59% (Predicate Device)**
Intended Use	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 are presbyopic.	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 are presbyopic.	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
Indications	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Production Method	Fully molded	Fully molded	Fully molded	Fully molded
USAN name	hioxifilcon D	hioxifilcon A	hioxifilcon D	hioxifilcon A
Water Content (%)	54±2%	59±2%	54±2%	59±2%
Oxygen Permeability	18.42×10^{-11} $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$ (revised Fatt method)	20.76×10^{-11} $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$ (revised Fatt method)	14.86×10^{-11} $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$ (revised Fatt method)	19.62×10^{-11} $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$ (revised Fatt method)
FDA Group	FDA Group 2 (>50% H_2O, non-ionic polymer)	FDA Group 2 (>50% H_2O, non-ionic polymer)	FDA Group 2 (>50% H_2O, non-ionic polymer)	FDA Group 2 (>50% H_2O, non-ionic polymer)
Refractive Index (hydrated)	1.404	1.403	1.409	1.392