December 13, 2017

Tangible Science LLC
% Bret Andre
Consultant/Official Correspondent
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K172692
Trade/Device Name: Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 9, 2017
Received: November 17, 2017

Dear Bret 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172692

Device Name
Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens

Indications for Use *(Describe)*

The Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism.

The Tangible Hydrogel with Tangible Polymer (etafilcon A) TORIC Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 5.00 D or less of astigmatism.

The Tangible Hydrogel with Tangible Polymer (etafilcon A) MULTIFOCAL Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 2.50 D of ADD power and may have 1.00 D or less of astigmatism.

Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon 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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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: **K172692**

Applicant information:

Date Prepared:	November 9th, 2017
Name:	Tangible Science LLC
Address	173 Jefferson Drive Menlo Park CA 94025
Contact Person:	Vic McCray, MD President & CEO
Phone number:	1-650-241-1045
Consultant:	Bret Andre EyeReg Consulting, Inc. 6119 Canter Ln West Linn, OR 97068
Phone number	(503) 372-5226

Device Information:

Device Classification:	Class II
Product Code:	LPL, MVN
Classification Name:	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Common Name:	Lens, Contact, (Disposable)
Trade Name:	**Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens**

Predicate Devices:

Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses are substantially equivalent to the following predicate devices:

- "**UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear**"
  By UNICON Optical Co., LTD.
  510(k) number; K141917
  Primary Predicate
- "**Saview-Aqua 58 UV (etafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens"** By St. Shine Optical Co., Ltd.
  510(k) number; K132146
  Reference Predicate

Device Description:

The **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens** is available in an aspheric design and manufactured using the cast-molding process. The lenses consist of 58% water and 42% etafilcon A. The lens material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which are cross-linked with Trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo-polymerization.

The **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses** are available in a light blue tint ([Phthalocyaninato(2-)]copper) for visibility and handling. The lenses also contain a Benzotriazole ultraviolet (UV) absorbing monomer to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range (280 to 315 nm), and less than 30% in the UVA range (316 to 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 (etafilcon A) soft hydrophilic contact lens has an aspheric 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 lenses are supplied sterile in blister packages containing a buffered saline solution. Package labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

The Physical properties of the lens are:

Refractive Index (wet)	1.400
Visible Light Transmission	>98%
Surface Character	hydrophilic
Water Content	58 ±2%
Specific Gravity	1.14 (hydrated)
Oxygen Permeability	29.96 x 10^{-11} (cm^2/sec) (ml O_2/ml-mmHg)

The lenses will be manufactured in the aspheric, toric, and multifocal design configurations with the following properties:

• Chord Diameter	12.0 mm to 15.00 mm
• Center Thickness	0.01 mm to 0.20 mm
• Base Curve	7.85 mm to 10.0 mm
• Power Range	+6.00D to -10.00D (in 0.25D steps)
- Cylinder	-0.75D to -2.50D (in 0.25D steps)
- Axis	10° to 180° (in 10° steps)
- Add	+1.00D to +2.50D (in 0.50D steps)

Indication for Use:

The **Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC** Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism.

The **Tangible Hydrogel with Tangible Polymer (etafilcon A) TORIC** Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 5.00 D or less of astigmatism.

The **Tangible Hydrogel with Tangible Polymer (etafilcon A) MULTIFOCAL** Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 2.50 D of ADD power and may have 1.00 D or less of astigmatism.

Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon removal.

Testing:

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses** packaged in blister packaging. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols.

Test results of the non-clinical testing on the **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses** demonstrate that:

- Lenses supplied in blister packages are sterile for the indicated shelf-life,
- The finished lenses, packaging material and extracts are non-toxic and non-irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

The safety and effectiveness of finished contact lenses manufactured from the etafilcon A material have been established previously through clinical performance testing.

Conclusions Drawn from Studies

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, Microbiology, chemistry, shelf-life stability studies and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens** is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of daily wear soft contact lenses. The benefits to the patient are the same as those for other soft contact lenses.

Substantial Equivalence:

The following matrix illustrates the production method, lens function and material characteristics of the **Tangible Hydrogel with Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens**, as well as the predicate devices.

Substantial Equivalence Matrix

	Tangible Hydrogel w/ Tangible Polymer (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens New Device	**UNICON (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear Predicate Device 510(k) K141917**	**Saview-Aqua 58 UV (etafilcon A) Soft (Hydrophilic) Contact Lens Predicate Device 510(k) K132146**
Intended Use	Indicated for the correction of ametropia (myopia and hyperopia) and/or are presbyopic in aphakic or non-aphakic persons with non-diseased eye who may have 5.00 D or less astigmatism.	Indicated for the correction of ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eye who may have 1.00 D or less astigmatism.	Indicated for daily wear for the correction of visual acuity in aphakic and not apjakic persons with non-diseased eyes with myopia or hyperopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.
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
Indications	Daily disposable. Soft (hydrophilic) Contact Lens	Daily wear. Soft (hydrophilic) Contact Lens	Daily wear. Soft (hydrophilic) Contact Lens
Production Method	Cast-Molded	Cast-Molded	Cast-Molded
USAN Name	etafilcon A	etafilcon A	etafilcon A
Water Content (%)	58%	58%	58%
Oxygen Permeability	29.96 x 10^{-11} (cm2/sec) (ml O2/ml-mmHg)	30.8 x 10^{-11} (cm2/sec) (ml O2/ml-mmHg)	26.3 x 10^{-11} (cm2/sec) (ml O2/ml-mmHg)
Color	[Phthalocyaninato(2-)]copper	[Phthalocyaninato(2-)]copper	Pigment blue 15
UV Blocking	Yes	Yes	Yes