DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 19, 2014

Synergeyes, Inc.
Steven L. Ziemba, M.Sc.
V.P., Quality Assurance & Regulatory Affairs
2232 Rutherford Road
Carlsbad, CA 92008

Re: K142510
Trade/Device Name: UltraHealth™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for Keratoconus
UltraHealth™ Flat Cornea SiH (petrafocon A Hem-larafilcon A) Hybrid Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lenses
Regulatory Class: Class II
Product Code: HQD
Dated: September 18, 20014
Received: September 22, 2014

Dear Mr. Ziemba:

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" (21CFR 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 Y. Alexander -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)*
K142510

Device Name
Device Names: UltraHealth SiH (petrafocon A hem-larafilcon A) Hybrid Contact lens for Keratoconus
UltraHealth Flat Cornea SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses

Indications for Use *(Describe)*

UltraHealth™ (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for keratoconus are indicated for the correction of hyperopic, myopic and astigmatic refractive error including presbyopia that manifest irregular corneas or irregular astigmatism, in aphakic and not aphakic, and otherwise non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and –20.00 D in eyes with irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D. The lenses may be disinfected using a chemical disinfecting system compatible with both silicone-hydrogel and rigid gas permeable lenses.

UltraHealth™ Flat Cornea SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses are for use in the correction of eyes with refractive errors resulting from corneal surgery or trauma including hyperopia and myopia, astigmatism and irregular astigmatism in aphakic and not aphakic, nondiseased eyes, with or without presbyopia. The lenses are indicated for daily wear for the correction of up to +20.00 and –20.00 D in eyes with irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D. The lenses may be disinfected using a chemical disinfecting system compatible with both silicone-hydrogel and rigid gas permeable lenses.

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
K142510

Date Prepared 04 November 2014

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Establishment Registration Number: 3005087645

Device Name:
Trade & USAN Names:
UltraHealth™ SiH Hybrid Contact Lenses for Keratoconus
UltraHealth™ Flat Cornea SiH Hybrid Contact Lenses

Common Name: Contact Lens
Classification Panel: Ophthalmic
Device Classification: Daily Wear Soft (hydrophilic)/RGP (hydrophobic) Combination Contact lens, Class II (21 CFR 886.5916)
Device Product Code: 86 HQD

Indications for Use:
The UltraHealth™ Hybrid Contact lens for Keratoconus for daily wear are indicated for use in the correction of hyperopic, myopic and astigmatic refractive error including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and -20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

The UltraHealth™ Flat Cornea Hybrid Contact Lenses for daily wear are indicated for use in the correction of eyes with refractive errors resulting from corneal surgery or trauma including hyperopia and myopia, astigmatism, and irregular astigmatism, including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and -20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and

+4.00 D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

Device Description

The UltraHealth™ SiH Hybrid Contact lens for Keratoconus and the UltraHealth™ Flat Cornea SiH Hybrid Contact Lenses are contact lenses that combine a gas permeable optic surrounded by a soft hydrophilic skirt that straddles the limbus of the eye:

- in the power range of -20.00 to +20.00 diopters for sphere,
- with center thickness from 0.16 mm to 0.39 mm
- with base curves of 5.5 mm to 9.00 mm
- with diameter of 14.50mm

When placed on the human cornea, the UltraHealth™ Hybrid Contact lens for Keratoconus and the UltraHealth™ Flat Cornea act as a refracting medium to focus light rays onto the retina. The devices are available as lathe cut contact lenses in the following designs: spherical, toric, multifocal, and aspheric surfaces in blue visibility tinted material.

The optics of the UltraHealth™ Hybrid Contact lens for Keratoconus and the UltraHealth™ Flat Cornea lenses are a gas permeable polymer material (petrafocon A). The soft skirt is comprised of silicone hydrogel (hem-larafilcon A) with a 32% water content. The junction between the rigid material and soft material is bound by a proprietary method.

Substantial Equivalence

For design: The hybrid (RGP Center and soft skirt) reverse geometry designs were cleared for the predicate SynergEyes™ (paflufocon D-hem iberfilcon A) Hybrid Contact Lenses in K056275 and K060102. The new lenses, the UltraHealth™ SiH (petrafocon A hem-larafilcon A) hybrid contact lenses for keratoconus, and the UltraHealth™ Flat Cornea SiH (petrafocon A hem-larafilcon A) hybrid contact lenses have the same substantially equivalent reverse geometry lens designs as the predicate lenses.

For material: The lens materials are comprised of a silicone Rigid Gas Permeable (RGP) center optic, and a soft silicone hydrogel skirt that surrounds the center optic zone which match the materials cleared under K083921. Biocompatibility, optical performance and safety of the materials for use in daily wear contact lenses were addressed in that submission.

For Optics:

The aspheric anterior optic surface matches that of the lenses cleared under K083921 and K051035.

Characteristics:

UltraHealth™ SiH Hybrid Contact Lenses for Keratoconus

	NEW LENS	PREDICATE LENS	REFERENCE LENS
Lens Characteristics	UltraHealth™ SiH Hybrid Contact Lenses for Keratoconus	Synergeyes KC (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Keratoconus (K052675)	Synergeyes SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens (K083921)
Manufacturer	Synergeyes, Inc.	Synergeyes, Inc.	Synergeyes, Inc.
Material	RGP Center: petrafocon A Soft Skirt: hem-larafilcon A	RGP Center: paflufocon D Soft Skirt: hem-iberfilcon A	RGP Center: petrafocon A Soft Skirt: hem-larafilcon A
UV Blocking	Yes	No	Yes
Base Curves (varies with vault)	5.5 mm to 9.0 mm	5.5 to 7.0 mm	7.1 to 9.0 mm
Base Curve Chord	6.0 mm to 6.5 mm	6.0 mm	6.0 mm to 6.5 mm
Design	Reverse geometry with anterior aspheric surface	Reverse geometry with anterior aspheric surface	Standard geometry with anterior aspheric surface
RGP Center	8.40mm	8.40mm	8.40 mm
Diameters:	14.5mm	14.5mm	14.5 mm
Power Range	-20.00 to +20.00	-20.00 to +20.00	-20.00 to +20.00
Add Powers (for multifocal)	+1.00 D to +4.00 D	+1.00 D to +4.00 D	+1.00 D to +4.00 D
Refractive Index (RGP)	RGP Center: 1.442 S/H Skirt: 1.435	RGP Center: 1.442 S/H Skirt: 1.448	RGP Center: 1.442 S/H Skirt: 1.435
Specific Gravity (RGP)	1.15	1.10	1.15
Hardness (Shore D)	RGP: 76	RGP: 79	RGP: 76
Modulus (kgf/cm^2) RGP Center	14515.1 ±324	11137.9 $\pm$ 367	14515.1 ±324
Tint	Visibility violet (D&C 2)	Visibility green (D&C Green #6)	Visibility violet (D&C 2)
Water Content (Soft Skirt)	<1%	<1%	28%
Lens Type	Group 1 Low Water	Group 1 Low Water	Group 1 Low Water

UltraHealth™ Flat Cornea

	NEW LENS	PREDICATE LENS	REFERENCE LENS
Lens Characteristics	UltraHealth™ Flat Cornea SiH Hybrid Contact Lenses	SynergEyes® PS (paflufocon D hem-iberfilcon A) Hybrid Contact Lenses for Post Surgical Refractive Error and Trauma (K060102)	Synergeyes® SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens (K083921)
Manufacturer	Synergeyes®, Inc.	Synergeyes®, Inc.	Synergeyes®, Inc.
Material	RGP Center: petrafocon A Soft Skirt: hem-larafilcon A	RGP Center: paflufocon D Soft Skirt: hem-iberfilcon A	RGP Center: petrafocon A Soft Skirt: hem-larafilcon A
UV Blocking	Yes	No	Yes
Base Curves (varies with vault)	5.5 mm to 9.0 mm	5.5 to 7.0 mm	7.1 to 9.0 mm
Base Curve Chord	6.0 mm to 6.5 mm	6.0 mm	6.0 mm to 6.5 mm
Design	Reverse geometry with anterior aspheric surface	Reverse geometry with anterior aspheric surface	Standard geometry with anterior aspheric surface
RGP Center	8.40mm	8.40mm	8.40 mm
Diameters:	14.5mm	14.5mm	14.5 mm
Power Range	-20.00 to +20.00	-20.00 to +20.00	-20.00 to +20.00
Add Powers (for multifocal)	+1.00 D to +4.00 D	None	+1.00 D to +4.00 D
Refractive Index (RGP)	RGP Center: 1.442 S/H Skirt: 1.435	RGP Center: 1.442 S/H Skirt: 1.448	RGP Center: 1.442 S/H Skirt: 1.435
Hardness (Shore D)	RGP: 76	RGP: 79	RGP: 76
Modulus (kgf/cm^2) RGP Center	14515.1 ±324	11137.9 $\pm$ 367	14515.1 ±324
Tint	Visibility violet (D&C 2)	Visibility green (D&C Green #6)	Visibility violet (D&C 2)
Water Content (Soft Skirt)	<1%	<1%	28%
Lens Type	Group 1 Low Water	Group 1 Low Water	Group 1 Low Water

Non-Clinical Studies

The lens materials are comprised of the same silicone Gas Permeable optic, and a soft silicone hydrogel skirt that surrounds the optic as was described in K083921. Biocompatibility testing (including Cytotoxicity, Ocular Irritation, Systemic Toxicity, and 21 Day Ocular Safety in Rabbits) as well as chemical, mechanical and optical characteristics, clinical performance and safety of the silicone hydrogel materials for use in daily wear contact lenses were addressed in K083921 per the FDA Contact Lens Daily Wear Guidance Document, May 1994.

Clinical Studies

The safety and effectiveness of the design of the new lenses is the same as the design for lenses cleared under K056275 and K060102. Daily wear contact lenses for keratoconus with the Synergeyes reverse geometry design were shown to be safe and effective in clinical studies submitted in K052675 and daily wear contact lenses for post surgical refractive error and trauma were shown to be safe and effective in clinical studies submitted in K060102; both conducted per the FDA Contact Lens Daily Wear Guidance Document, May 1994.

The materials, processing, lens specifications, packaging and sterilization for the UltraHealth™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact lens for Keratoconus and the UltraHealth™ Flat Cornea SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses are identical to those described in K083921, which includes data to support that the materials and processing methods are biocompatible, safe and effective for use in daily wear contact lenses.

Packaging

The primary lens container for shipping is a sterile enclosed medical grade glass vial with a screw cap and rubber stopper and sterilized using an e-beam process. The lens is immersed in a sterile, phosphate-buffered saline.

Manufacturing & Sterilization

The same manufacturing and sterilization locations described for the predicate lenses are used for these new lenses.

Relationship to Special Controls (Guidance)

The Contact Lens Daily Wear Guidance Document, May 1994, is the relevant document to which this submission is based.