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

August 1, 2016

SynergEyes, Inc.
% Mr. Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Re: K160938
Trade/Device Name: SynergEyes® SiH with Hydra-PEG (petrafocon A Hem-larafilcon A) Hybrid Daily Wear Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: June 20, 2016
Received: June 23, 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 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)*
K160938

Device Name
SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lens

Indications for Use *(Describe)*
The SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses 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 +25.00 and -25.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 D and +4.00 D.

The SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear 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 +25.00 and -25.00 Din eyes with irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D.

The SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses 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 in aphakic and not aphakic, non-diseased eyes with or without presbyopia. The lenses are indicated for daily wear for the correction of up to +25.00 and -25.00 Din eyes with astigmatism or irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using only a chemical (not heat) 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: **K160938**

Applicant information:

Date Prepared:	April 27th, 2016
Name:	SynergEyes, Inc.
Address	5927 Priestly Drive, Suite 210, Carlsbad, CA 92008
Contact Person:	James Kirchner, O.D. President/CEO
Phone number:	(877)733-2012
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:	HQD
Classification Name:	Daily Wear Rigid Gas Permeable Contact Lens (21 CFR 886.5916)
Trade Name:	**SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lens**

Purpose of 510(k) Submission:

~ New Technology ~

The SynergEyes® SiH (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses—cleared under 510(k) K083921 and K113586—are modified to include Hydra-PEG Technology (HPT), which is a thin, polyethylene glycol (PEG)-based polymer designed to improve the wettability of the contact lenses. Specifically, HPT treated contact lenses demonstrate a measureable improvement in the contact angle in comparison with the untreated lenses. The application of HPT to the surface of SynergEyes® SiH contact lenses does not change the design or indications for use in comparison with the untreated lenses, the predicate device (K083921 and K113586).

Predicate Devices:

The **SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses** are substantially equivalent to the following predicate devices:

"**SynergEyes® SiH (petrafocon A hem-larafilcon A)**"
By SynergEyes, Inc.
510(k) number; **K083921 and K113586**
-primary predicate

"**IntelliWave4 with HPT (safrofilcon A)**"
by Art Optical Contact Lens, Inc.
510(k) number; **K152046**
-reference predicate

"UltraHealth® SiH (petrafocon A hem-larafilcon A)"
By SynergEyes, Inc.
510(k) number; **K142510**
-reference predicate

Device Description:

The **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** is a combination of high Dk rigid gas permeable contact lens—at the central optical portion of the lens corresponding to the cornea—and soft hydrophilic silicone-hydrogel skirt—straddling the limbus of the eye peripherally. The lenses are manufactured by lathe cutting process for custom R_x, and fabricated from petrafocon A (rigid, central portion) and hem-larafilcon A (soft, peripheral portion). The soft skirt is comprised of silicone hydrogel copolymer (hem-larafilcon A). The lens consists of 28% water and 72% (petrafocon A and hem-larafilcon A). The (petrafocon A and hem-larafilcon A) names have been adopted by the United States Adopted Names Council (USAN). When placed on the human cornea, the **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** acts as a refractive medium to focus light rays onto the retina.

The **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** incorporates a violet visibility tint in the rigid gas permeable center, and a UV absorber. The device is available in the spherical, aspheric, multifocal (progressive), post-surgical, & irregular cornea design configurations

with the following properties:

- Chord Diameter 13.0 mm to 25.00 mm
- Center Thickness 0.050 mm to 0.500 mm
- Base Curve 5.50 mm to 9.50 mm
- Power Range (sphere) -25.00D to +25.00D
- Add Power +1.00D to +4.00D

The Physical properties of the lens are:

	RGP Center	**Soft Skirt**
Refractive Index (wet)	1.442	1.435
Luminous Transmittance (tinted) (380nm to 780)	87%	97%
Surface Character	hydrophobic	hydrophilic
Water Content	28 ± 2%	
Specific Gravity	1.15	N/A
Oxygen Permeability (revised Fatt method)	130	84

The **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** is treated to incorporate Hydra-PEG Technology (HPT)—which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material (petrafocon A hem-larafilcon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. The following table depicts the enhanced contact angle of the **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** versus the predicate device:

Wettability -- captive bubble contact angle (degrees) (advancing contact angle)*		
Lens	**Average**	**Stdev**
SynergEyes® SiH with Hydra-PEG (New Device)	21.75°	2.2
SynergEyes® SiH (Uncoated) (Predicate Device)	33.50°	9.5

* Hydra-PEG coated lenses demonstrate a 35% improvement in wettability vs. uncoated lenses (n = 20). Statistically significant difference for mean contact angle with respect to lens, where the coated lenses had a lower average contact angle than the un-coated lenses (ANOVA, p=0.000)

The lens is supplied sterile in vials containing a buffered saline solution. Vial 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.

Intended Use:

The **SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses** 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 +25.00 and –25.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 D and +4.00 D.

The **SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear 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 +25.00 and –25.00 D in eyes with irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D.

The **SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lenses** 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 in aphakic and not aphakic, non-diseased eyes with or without presbyopia. The lenses are indicated for daily wear for the correction of up to +25.00 and –25.00 D in eyes with astigmatism or irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using only a chemical (not heat) disinfecting system compatible with both silicone-hydrogel and rigid gas permeable lenses.

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 **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** packaged in glass vials. 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 **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** demonstrate that:

- Lenses supplied in glass vials are stable for the indicated shelf-life,
- The finished lenses with Hydra-PEG are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

The clinical safety and effectiveness has been previously established for hybrid contact lenses manufactured from (petrafocon A hem-larafilcon A) and contact lenses treated with Hydra-PEG.

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 **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear 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 hybrid daily wear contact lenses. The benefits to the patient are the same as those for other hybrid contact lenses.

Substantial Equivalence:

Comparison to Predicate Device(s):

The **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** is substantially equivalent to the SynergEyes® SiH (cleared under K083921 and K113586) and UltraHealth® SiH (cleared under K142510) in terms of the following:

- contact lens material (petrafocon A hem-larafilcon A)
- lathe cut manufacturing process
- manufacturing facility
- sterilization process and final packaging
- designs and indications

The **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens** is substantially equivalent to the IntelliWave4 with HPT (cleared under K152046) in terms of the following:

- processed to incorporate Hydra-PEG coating

The following matrix illustrates the production method, lens function and material characteristics of the **SynergEyes® SiH with Hydra-PEG Hybrid Daily Wear Contact Lens**, as well as the predicate devices.

Substantial Equivalence Matrix

	SynergEyes® SiH with Hydra-PEG (petrafocon A hem-larafilcon A) New Device	**SynergEyes® SiH, and UltraHealth® SiH (petrafocon A hem-larafilcon A) (uncoated) Predicate Device (K142510, K083921 and K113586)**	**Art Optical IntelliWave4 with HPT, Silicone Hydrogel (safrofilcon A) Predicate Device (K152046)**
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. 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 Wear	Daily Wear	Daily Wear
Production Method	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured
USAN name	petrafocon A hem-larafilcon A	petrafocon A hem-larafilcon A	safrofilcon A
Water Content (%)	28±2%	28±2%	65±2%
Wettability (captive bubble advancing contact angle)	21.75°	33.50°	46°
Specific Gravity	1.150	1.150	1.102
Includes Hydra-PEG Surface Coating	Yes	No	Yes