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

November 15, 2016

Synergeyes, Inc.
% Richard Lippman, OD, FAAO
Regulatory Consultant
R.E. Lippman Regulatory Pathways
1171 Kersey Road
Silver Spring, MD 20902

Re: K153714
Trade/Device Name: SynergEyes™ A&M Hybrid Contact Lenses
SynergEyes™ KC and ClearKone™ Hybrid Contact Lenses
SynergEyes™ PS Hybrid Contact Lenses
SynergEyes™ Duette (SiH) Hybrid Contact Lenses
SynergEyes™ Ultrahealth™ Hybrid Contact Lenses for Keratoconus Hybrid Contact Lenses
SynergEyes™ Ultrahealth™ Flat Cornea Hybrid Contact Lenses for Keratoconus

Regulation Number: 21 CFR 886.5926
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: September 30, 2016
Received: October 7, 2016

Dear Dr. Lippman:

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)*
K153714

Device Name
SynergEyes™ A & M Hybrid Contact Lenses

Indications for Use *(Describe)*

SynergEyes™ A (paflufocon D hem-iberfilcon A) and SynergEyes™ M (paflufocon D hem-iberfilcon A) Hybrid 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 indicted 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 prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

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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See PRA Statement below.

510(k) Number *(if known)*

K153714

Device Name

SynergEyes™ KC and ClearKone™ Hybrid Contact Lenses

Indications for Use *(Describe)*

SynergEyes™ KC (paflufocon D hem-iberfilcon A) and ClearKone™ (paflufocon D hem-iberfilcon A) Daily Wear Hybrid Contact Lenses for keratoconus are indicated for use in the correction of eyes with refractive errors that include hyperopia and myopia that manifest 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. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

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) Number *(if known)*

K153714

Device Name

SynergEyes™ PS Hybrid Contact Lenses

Indications for Use *(Describe)*

SynergEyes™ PS (paflufocon A hem-iberfilcon A) Hybrid 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. 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. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

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) Number *(if known)*

K153714

Device Name

SynergEyes™ Duette (SiH) Hybrid Contact Lenses

Indications for Use *(Describe)*

Duette™ (SiH) (petrafocon A hem-larafilcon A) Hybrid Contact Lenses 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 prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat), prior to reinsertion, as recommended by the eye care professional.

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) Number *(if known)*

K153714

Device Name

SynergEyes™ UltraHealth™ Hybrid Contact Lenses for Keratoconus 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 prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

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) Number *(if known)*
K153714

Device Name

SynergEyes™ UltraHealth™ Flat Cornea Hybrid Contact Lenses for Keratoconus

Indications for Use *(Describe)*

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, non-diseased eyes, with or without presbyopia. The lenses are indicated for daily wear 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 prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

Type of Use *(Select one or both, as applicable)*

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