



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

SynergEyes, Incorporated
c/o Richard E. Lippman, O.D.
VP Ophthalmic Product Regulatory Affairs
Official Correspondent to SynergEyes, Inc.
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Road, Suite 30
Rockville, MD 20850

APR 18 2012

Re: K113586

Trade/Device Name: Duette SiH (petrafocon A hem-larafilecon A) Hybrid Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Codes: HQD
Dated: March 26, 2012
Received: March 28, 2012

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K113586

Indications for Use

510(k) Number (if known): K113586

Device Name: Duette™ SiH (petrafocon A hem-laraofilcon A) Hybrid Contact lens

Indications For Use:

Duette™ SiH (petrafocon A hem-laraofilcon 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 not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robbey
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices.

510(k) Number K113586