



MAR - 5 2008

SynergEyes, Inc.  
c/o Richard E. Lippman, O.D.  
Vice President for Ophthalmic Product Regulatory Affairs  
R.P. Chiacchierini & Associates, LLC  
15825 Shady Grove Road, Ste. 30  
Rockville MD 20850

Re: K080193

Trade/Device Name: SynergEyes™ A, M, KC, and PS (paflucocon D hem-iberfilcon A)  
Hybrid Daily Wear Contact Lens  
Regulation Number: 21 CFR 886.5916  
Regulation Name: Rigid gas permeable contact lens  
Regulatory Class: II  
Product Code: HQD  
Dated: January 25, 2008  
Received: January 25, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

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| SYNERGEYES, INC.<br>510(k) Premarket Notification  | SECTION 4  |
| SynergEyes™ A (paflucocon D hem-iberfilcon A)<br>Hybrid Contact lens for Ametropia<br>SynergEyes™ M (paflucocon D hem-iberfilcon A)<br>Hybrid Contact lens for Presbyopia<br>SynergEyes™ K (paflucocon D hem-iberfilcon A)<br>Hybrid Contact lens for Keratoconus<br>SynergEyes™ PS (paflucocon D hem-iberfilcon A)<br>Hybrid Contact lens for Post Surgery and Trauma | INDICATIONS FOR USE STATEMENT<br>Daily Wear Contact Lens |

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) \_\_\_\_\_

Device Names: SynergEyes™ – A, M, KC, and PS (paflucocon D hem-iberfilcon A) Hybrid Daily Wear Contact Lens

Indications for Use

SynergEyes™ A and M (paflucocon D hem-iberfilcon 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 D and +4.00 D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

SynergEyes™ KC (paflucocon D hem-iberfilcon A) 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 10.00 D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

SynergEyes™ PS (paflucocon D 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 eyes with irregular astigmatism up to 6.00 D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_ OR Over-the-counter-use \_\_\_\_\_

  
 (Division Sign-Off)  
 Division of Ophthalmic Ear,  
 Nose and Throat Devices

(Division Sign-off)  
 510(k) Number \_\_\_\_\_

510(k) Number K080193