K060102

SynergEyes™, Inc.
Carlsbad, CA 92008

MAR 15 2006

510(K) SUMMARY

Applicant's Name and Address

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Contact Person

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1. Identification of device

Common Name:	Contact Lens
Trade Name:	SynergEyes™ PS (paflufocon D hem-iberfilcon A) Hybrid Daily Wear Lens For Post Surgical and Trauma
Classification:	Daily Wear Contact Lens (other material)
Device classification:	Class II (21 CFR 886.5916)

2. Description of device

The SynergEyes™ PS (paflufocon D hem-iberfilcon A) Hybrid Daily Wear Contact Lens is a combination rigid gas permeable contact lens corneal optic portion 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
- in the range of 0.25 to 6.00 diopters cylinder
- with center thickness from 0.18mm to 0.30mm
- with base curves of 7.10mm to 9.60mm
- with diameter of 14.50mm

The lens material (paflufocon D hem-iberfilcon A) is identical to the predicate current material cleared under K051035 and K052675. There are no differences to the chemical composition, formulation, manufacturing process, packaging and sterilization as described in the referenced 510(k).

This lens material for the rigid portion is paflufocon D lathe cut, surrounded by soft hydrophilic copolymer (hem-iberfilcon A), sterilized by means of e-beam sterilization. When placed on the human cornea, the SynergEyes™Hybrid Contact Lens acts as a refracting medium to focus light rays onto the retina. The device is available as a lathe cut contact lens in the following design for post surgical refractive errors and trauma: multi concentric zones in blue visibility tinted material. This device is equivalent to the SynergEyes™ A and M Hybrid Contact Lens is material design and composition, and the SoftPerm® hybrid RGP manufactured by Ciba Vision Corporation.

The SynergEyes™ PS Hybrid Daily Wear Contact Lens center optical portion is a rigid gas permeable material of (paflulofon-D) polymer. The soft skirt is comprised of HEMA (hydroxyethylmethacrylate) of 27% water and 73% polymer.

The junction between the rigid material and soft material is bound by a proprietary chemical bonding method.

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3. Intended use

SynergEyes™ PS (paflufocon 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 in eyes with astigmatism or 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.

4. Predicate devices

The predicate lens SynergEyes™ A and M (paflufocon D hem iberfilcon A) Hybrid Contact Lenses were selected to address material use and design (rigid lens center and soft lens skirt).

The material portion is equivalent to the predicate lenses. The optic center rigid portion of the lens is a silicone acrylate- paflufocon D used in the cleared predicates K051035 and K052675 as well as referenced HDS material from Paragon Vision Sciences P870024/S36 and 43.

The soft skirt portion of the subject device, hem-iberfilcon A, a Group I low water non-ionic material, is equivalent to its predicate K051045 and K052675.

Further equivalence to predicate devices for indication for use and parameter comparison may be found in the equivalence matrix below.

Predicate Devices:

- For the Hybrid (RGP-soft skirt concept):

SynergEyes™, Inc.	K051035	Cleared: 9/2/2005
	K052675	Cleared: 11/30/2005
SoftPerm (synergicon A) Mixed use Lens	P840004/S7	App: 10/14/1993

- For the RGP Center Portion:

SynergEyes™, Inc.	K051035	Cleared: 9/2/2005
	K052675	Cleared: 11/30/2005
Paragon Vision Sciences	P870024/S36 and S43 (App: 11/23/1993 and 4/13/2002)	
	K940277	Cleared: 5/9/1994

- For the Soft Skirt Portion:

SynergEyes™, Inc.	K051035	Cleared: 9/2/2005
	K052675	Cleared: 11/30/2005
SoftPerm (synergicon A) Mixed use lens	P840004/S7	App: 10/14/1993

5. Characteristics
The physical and dimensional characteristics of the SynergEyes™ PS Hybrid Contact Lens are compared to the characteristics of the predicate devices SynergEyes™ A and M lenses, and SoftPerm® Contact Lens in the following table.

Lens Characteristics	SynergEyes™ PS (paflufocon D-iberfilcon A) Hybrid Contact Lens (Subject Device)	SynergEyes™ A and M (paflufocon D-iberfilcon A) Hybrid Contact Lens K051035 (Predicate Device)	SoftPerm® (synergicon A) Contact Lens P840004/S7 (Predicate Lens)
Manufacturer	SynergEyes™ Inc.	SynergEyes™ Inc.	Ciba Vision Care
Base Curves	7.10-9.60mm	7.10-9.00mm	7.10-8.10mm
RGP Center	9.00mm	8.40mm	8.00mm
Posterior Optic Zone Diameter	8.40mm	7.80mm	7.00mm
Lens Designs	Sphere, Aspheric, Front Surface Toric,	Sphere, Aspheric, Front Surface Toric, Multifocal	Sphere, Front Surface Toric
Diameters:	14.5mm	14.5mm	14.3mm
Power Range	-20.00 to + 20.00D	-20.00 to + 20.00D	-13.00 to +6.00D
Cylinder Power Range	0.50 to 6.00D	0.50 to 10.00D	
Add Power for Near		0.75 to 3.00D	
Center Thickness	0.18 to 0.30mm	0.12 to 0.30mm	0.08mm to 0.28mm
Refractive Index (RGP)	1.442 (Nd @ 25°C)	1.442 (Nd @ 25°C)	1.53
Wetting Angle (RGP)	42°	42°	21° CLMA
Specific Gravity (RGP)	1.10	1.10	1.015
Hardness	79	79	
Indications for Use	Daily Wear	Daily Wear	Daily Wear
UV Blocking	No	No	No
Material	Paflufocon D center RGP hem-iberfilcon A (HEMA, MEMA)	Paflufocon D center RGP hem-iberfilcon A (HEMA, MEMA)	Synergicon A RGP and HEMA Skirt
Tint	Visibility Blue	Visibility Blue	Clear
Soft Skirt Water Content	27%	27%	25%
Core (RGP) Water Content	< 1%	< 1%	< 0.2%

6. Non clinical studies:

Results from the full series of physical/chemical, toxicological, and sterility tests were conducted under K051035 for the equivalent lens, the predicate lens for this device. No further non-clinical studies were performed for this submission.

7. Packaging

The primary lens container for shipping is a sterile enclosed medical grade glass vial capped with a screw cap and sterilized with the e-beam sterilization process. The lens is immersed in a sterile buffered normal saline.

8. Clinical data:

A three month clinical study of the SynergEyes™ PS Hybrid Contact Lens was conducted to assess safety and effectiveness for vision correction in daily wear for patients suffering from post surgical refractive error including nearsightedness, farsightedness, astigmatism and irregular astigmatism, or trauma to the eye. The study was designed to evaluate contact lens visual acuity and wearing time; and assess contact lens adverse events and loss of visual acuity.

Overall Findings:

A total of 76 subjects were dispensed into the study of which 44 (80 eyes) [57.9%] completed the study and 32 subjects (58 eyes) [42.1%] were discontinued from the study. An additional 8 subjects were not dispensed lenses.

The population demographics were similar to other contact lens studies with a female to male gender ration of 1.3 to 1.0. The average age of the completed and discontinued subjects was 49 and 43.5 respectfully.

Safety:

Eight (8) adverse events were reported during the study for 4 completed subjects and 3 discontinued subjects. The adverse events included 1 painful light sensitivity (photophobia); 1 loose interrupted suture and infiltrate; 1 abrasion of the cornea upon lens removal; 1 small superficial abrasion; 1 subject (2 eyes) with swelling of the corneas due to inadequate rinsing of hydrogen peroxide disinfection solution from lenses; 1 allergic conjunctivitis; and 1 keratitis iritis.

Thirty-two (32) subjects (58 eyes) [42.1%] were discontinued from the study. An additional 8 subjects were never dispensed lenses. The most common reasons for discontinuation were poor outcome with lenses (32.5%), poor comfort (27.5%), poor vision (12.5%), loss of interest (10.0%), non-compliance (10.0%), and handling difficulty (2.5%).

Symptoms, Problems, and Complaints: For the completed eyes, no symptoms were reported at 46.2% of the dispensing visit or follow-up visit examinations and for discontinued eyes no symptoms were reported at 28.8% of the dispensing visit or follow-up visit examinations. Symptoms decreased over time for completed eyes but not for discontinued eyes. The most common symptoms reported were discomfort and awareness (28.4% completed, 45.8% discontinued), dryness and scratchiness (23.4%, 22.1%), itchiness and burning (9.3%, 8.9%), and variable vision (8.2%, 13.3%).

Efficacy:

Visual Acuity- Final visual acuity for completed subjects was 20/20 or better (20.0%), 20/25 or better (45.0%), 20/30 (68.8%), and 20/40 or better (81.3%). The visual acuity rates for discontinued subjects were 8.6%, 39.7%, 53.4%, and 70.7% respectfully. Vision correction fluctuated as expected with the instability of the corneal curvature from post surgical conditions and trauma under the contact lens contributing to the change. Three (3) completed eyes and 8 discontinued eyes were reported to have VA decreases of more than 2 lines of Snellen VA when comparing the contact lens VA with the best corrected VA. These findings are expected with this population.

For Wearing Time: Over the study period the average daily wearing time reported by completed patients was 10.6 hours per day.

Conclusion:

The SynergEyes™ PS Hybrid Contact Lens for Post Surgical refractive error and cases involving trauma provided satisfactory performance as expected. The higher than estimated discontinuation rate was anticipated due to the nature of the subject population with the inclusion of subjects who might otherwise have less successful outcomes with other lens types. Overall, the lens performance demonstrated safe and effective use of the device for its intended use.

9. Conclusions drawn from studies
Substantial Equivalence:

Information provided in this 510(k) establishes that the SynergEyes™ PS Hybrid Contact Lens are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. The clinical evaluation demonstrated safe and effective lens performance, and where possible equivalence to historical experience with predicate devices. The device is substantially equivalent to the predicate devices material, SynergEyes A and M Hybrid Contact Lens (K051035), Paragon HDS-100 (P870024/S36 and

S43), and (K940277); and SoftPerm (synergicon A) contact lens (P840004/S7), and indication for use as a hybrid lens material comprised of a rigid center optic portion and a soft skirt portion.

Clinical Experience Equivalence to Other Studies

	SynergEyes™ PS Hybrid Contact Lens	Jurkus (1998)	Chung (2001)
No. of Lenses (Eyes)	80	21	35
No. Patients	75	11	28
Gender	42F/33M	5F/6M	11F/17M
Mean Age	49 (Completed)		41 + 19
Lens	SynergEyes PS	Saturn II	SoftPerm/Prior RGP users
Indication	Myopia, Hyperopia, Irr. Astimgatism	Astigmatism	Keratoconus 22/35 (62.9%) and PK 10/35 (28.8%)
Completions	44 (57.9%)	4 (36%)	17 (66.7%)
Discontinuations	32 (42.1%)	7 (64%)	11 (33.3%)
For Comfort	27.5%	28%	45.5%
For Vision	12.5%	28%	9.1%

Material Equivalence Table

	SynergEyes™ PS Hybrid Contact Lens for Keratoconus (Subject Device)	SynergEyes™ A and M Hybrid Contact Lens for Daily Wear (K051035)	SoftPerm® Contact Lens P840004/S7
PRODUCTION METHOD	Lathing	Lathing	Lathing
INTENDED USE	Daily Wear	Daily Wear	Daily Wear
MATERIAL	Paflufocon D Center hem-iberfilcon A skirt	Paflufocon D Center hem-iberfilcon A skirt	Synergicon-A
Type	Group 1 Low Water	Group 1 Low Water	Group 1 Low Water
Surface Charge	Non-ionic	Non-ionic	Non-ionic
Color additive	D&C Green 6	D&C Green 6	
UV additive	No	No	No
Dk permeability: **1. Revised FATT Polarimetric method with edge correction @ 35°C x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)** **2. ISO 9913-1**	RGP Center: FATT: 145 ISO: 100 - - - - - - - - - - - - - - - - - - Soft Skirt: 9.3	RGP Center: FATT: 145 ISO: 100 - - - - - - - - - - - - - - - - - - Soft Skirt: 9.3	RGP Center: ISO: 14 - - - - - - - - - - - - - - Soft Skirt: 5.5
Dk/L- Lens transmissibility: **1. Revised FATT (Through power range -20 to + 20D)** **2. ISO 9913-1 Polarimetric method :**	FATT: 66-77 ISO: 46-53	FATT: 66-77 ISO: 46-53	ISO: 17.5
Light transmittance (380nm to 780nm)	>90%	>90%	88-92%

Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of RGP and soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other RGP and soft (hydrophilic) contact lenses. Overall, the risks and benefits associated with daily wear contact lenses are the same as for other daily wear contact lenses and raise no additional concerns for safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

SynergEyes, Inc.
C/O Richard E. Lippman, O.D., F.A.A.O.
Vice President for Ophthalmic Product Regulatory Affairs
P. Chiacchierini & Associates, LLC
15825 Shady Grove Rd., Suite 30
Rockville, MD 20850

Re: K060102
Trade/Device Name: SynergEyes™ PS (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Post Surgical Refractive Error and Trauma for Daily Wear
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: January 13, 2006
Received: January 13, 2006

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 Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K060102

Device Name: SynergEyes™ PS (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Post Surgical Refractive Error and Trauma for Daily Wear

Indications For Use: 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 in eyes with astigmatism or irregular astigmatism up to 6.00D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Karen Wahlstrom

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

510(k) Number K060102