SEP - 2 2005

SynergEyes™, Inc.
Carlsbad, CA 92008

K051035

510 (K) SUMMARY

Applicant's Name and Address

SynergEyes, Inc.
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Carlsbad, CA 92008
(760) 476 9410

Contact Person

Richard Lippman, OD FAAO
Vice President Ophthalmic Regulatory Products
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1. Identification of device

Common Name:	Contact Lens
Trade Name:	SynergEyes™(paflufocon D hem-iberfilcon A) Hybrid Daily Wear Lens
Classification:	Daily Wear Soft (hydrophobic) Contact Lens
Device classification:	Class II (21 CFR 886.5916)

2. Description of device

The SynergEyes™ A and M (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,
- with center thickness from 0.12mm to 0.30mm
- with base curves of 7.10mm to 9.00mm
- with diameter of 14.50mm
-

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 designs: spherical, toric, multifocal, and aspheric surfaces in blue visibility tinted material. This device is equivalent to the SoftPerm® hybrid RGP with soft lens skirt manufactured by Ciba Vision Corporation.

The SynergEyes™ A and M Hybrid Daily Wear Contact Lens is a rigid gas permeable material of (paflulofon-D) rigid gas permeable 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.

3. Intended use

SynergEyes® A and M (paflufocon 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 and +4.00D. 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 lenses were selected to address: material (silicone acrylate- paflufocon D) for the optic portion of the lens and (synergicon A) for the soft skirt portion of the lens. Additionally for lens design (hybrid RGP/soft), lens group (silicone acrylate RGP and Group I low water non-ionic for the soft material. Further equivalence to predicate devices for indication for use and parameter comparison.

Predicate Devices:

- For the RGP Center Portion:

Paragon Vision Sciences		P870024/S39 and S43 K940277 K002845
Polymer Technology (B&L)	Boston XO:	K000795

- For the Hybrid (RGP-soft skirt concept)

Saturn II (synergicon A) Mixed use Lens	P840004

5. Characteristics

The physical and dimensional characteristics of the SynergEyes™ Hybrid Contact Lens are compared to the characteristics of the predicate device SoftPerm® Contact Lens in the following table.

Lens Characteristics	**SynergEyes™ (paflufocon D-iberfilcon A) Hybrid Contact Lens**	**SoftPerm® (synergicon A) Contact Lens (Predicate Lens)**
Manufacturer	SynergEyes™ Inc.	Ciba Vision Care
Base Curves	7.10-9.00mm	7.10-8.10mm
RGP Center	8.40mm	8.00mm
Posterior Optic Zone Diameter	7.80mm	7.00mm
Lens Designs	Sphere, Aspheric, Front Surface Toric, Multifocal	Sphere, Front Surface Toric
Diameters:	14.5mm	14.3mm
Power Range	-20.00 to + 20.00D	-13.00 to +6.00D
Center Thickness	0.12 to 0.30mm	0.08mm to 0.28mm
Refractive Index (RGP)	1.442	1.53
Wetting Angle (RGP)	42^{o}	21^{o} CLMA
Specific Gravity (RGP)	1.10	1.015
Hardness	79	
Indications for Use	Daily Wear	Daily Wear
UV Blocking	No	No
Material	Paflufocon D center	Synergicon A

	RGP hem-iberfilcon A (HEMA, MEMA)	RGP and HEMA Skirt
Tint	Visibility Blue	Clear
Soft Skirt Water Content	27%	25%
Core (RGP) Water Content	< 1%	< 0.2%

6. Non clinical studies
Non-clinical studies are summarized below:

Chemistry and leachability
- Material property data were generated on the SynergEyes™ and the Paragon HDS 100 materials. The material properties were substantially equivalent.
- The lens care product manufacturers have been previously shown compatible for RGP and soft (Hydrophilic) lenses with their products.
- The shelf life stability for the SynergEyes™ Hybrid Contact Lens is based upon stability protocols included with this notification.
- Studies were conducted to determine the residual monomers on the subject device.

Toxicology, lenses materials
In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the SynergEyes™ Hybrid Contact Lens. The results are summarized below:

- ***Cytotoxicity Test*:**

Cytotoxicity Tests have been conducted on the subject device according to ISO 10993-5: Biological Evaluation of Medical Devices- Tests for Cytotoxicity: In vitro Methods guidelines, was conducted on the test articles, to determine the potential for Cytotoxicity.
The negative controls and the positive controls performed as anticipated. Under the conditions of the study, the test articles were not cytotoxic.

- ***Acute Systemic Injection Test in the mouse*:**

An evaluation of the test articles for systemic toxicity in mice after a single intravenous administration or a single intraperitoneal administration has been conducted according to the ISO 10993-11: Biological Evaluation of Medical Devices. Tests for Systemic Toxicity.
No evidence of systematic toxicity was observed from the test article extracts. Each test article met the test requirements.

- ***Ocular Eye Irritation Test in the rabbit*:**

An evaluation of the ocular irritation of 0.9% NaCl of the subject article after a single instillation in the rabbit has been conducted according to ISO 10993-10: Biological Evaluation of Medical Devices. Tests for the Irritation and Sensitization.
No evidence of ocular irritation was observed in the rabbits. The test article extracts are not considered irritants to the ocular tissue of rabbits.

Validity of Scientific Data:
A contract laboratory using Good Laboratory Practices conducted the Toxicology studies. Chemistry leachables studies were conducted in-house. Certification as to implementation and conduct under Good Laboratory Practices may be found with each report.

Solution Compatibility
Lens materials used in this device are already recognized materials previously approved for use with all approved lens care products. No further testing was conducted.

Microbiology and sterilization

The SynergEyes™ Hybrid Contact Lenses are sterilized using e-Beam sterilization. Shelf-life sterility and stability has been established as 1 year as of the current date. Additional extensions of shelf life dating will be added in accordance with an approved protocol.

7. Packaging
The primary lens container for shipping is a sterile enclosed medical grade glass vial capped with a screw cap. The lens is immersed in a sterile buffered normal saline.

8. Clinical data

- A Clinical Study was performed to establish the safety and efficacy of the SynergEyes™ (paflufocon D hem-iberfilcon A) Hybrid Contact Lens. The clinical investigation of the SynergEyes™Hybrid Contact Lens was conducted on 107 subjects for a period of 3 months. All subjects read and signed an informed consent document regarding participation in the investigation which was conducted in conformance with US and international ethical standards and regulations. Sixty-one (61) [57%) subjects completed the protocol, 46 (43%) were discontinued. The reasons for discontinuation were as follows:

Reason For Discontinuation	Over All Visits	
	# Subjects	%
Poor Comfort	15	32.6%
Loss of Interest	13	28.3%
Poor Vision	6	13.0%
Difficulty Handling	1	2.2%
Other	3	6.5%
Medical Condition – not study related	2	4.3%
Non-Compliance	4	8.7%
Poor Outcome with Lenses	2	4.3%
Total Eyes	46	

The "other" reasons included travel conflicts (1), use of reading glasses inconvenient (1), and subject not happy with lenses (1).

- There was one complication reported as "Poor outcome with lenses" during the study, a corneal abrasion of one patient, both eyes. The subject was treated and was discontinued.

- Safety was assessed by adverse events, positive slit lamp findings, symptoms problems and complaints and changes in keratometric readings. There were no adverse events reported. Symptoms problems and complaints were minimal with comfort being the most prevalent finding although the complaint diminished with time. There were no other significant safety findings noted in the study. No visual acuity was lost during the course of the study.

- Efficacy was evaluated by changes in refractive correction, lens visual acuity, average wearing time. No significant changes were noted in efficacy upon evaluation of the data.

In conclusion, the SynergEyes™ Hybrid Contact Lens material performance is equivalent in safety and effectiveness to predicate contact lenses for this class of materials, as well as for RGP daily and soft daily wear lenses in general.

9. Conclusions drawn from studies
Substantial Equivalence:

SynergEyes™, Inc.
Carlsbad, CA 92008

Information provided in this 510(k) establishes that the SynergEyes™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, Paragon HDS under P870024/S39 and S43, and K940277; and SoftPerm (synergicon A) lens under P840004, and indication for use as a hybrid lens material comprised of a rigid center optic portion and a soft skirt portion.

Clinical Equivalence to Predicate Devices Historical Experience

	SynergEyes™ Hybrid Contact Lens	**Jurkus** (1998)	**Chung** (2001)
No. of Lenses (Eyes)	214	21	35
No. Patients	107	11	28
Gender	72F/32M	5F/6M	11F/17M
Mean Age	43F/39.9M		41 ± 19
Lens	SynergEyes™ Hybrid	Saturn II	SoftPerm-Prior RGP users
Indication	Myopia, Hyperopia, Astigmatism	Astigmatism	Keratoconus 22/35 (62.9%) PK 10/35 (28.6%)
Completions	61 (57%)	4 (36%)	17 (66.7%)
Discontinuations	46 (43%)	7 (64%)	11 (33.3%)
Comfort	32%	28%	45.5%
Vision	13%	28%	9.1%

Material Equivalence Table

Material Comparison		
	SynergEyes™ Hybrid Contact Lens	**SoftPerm® Contact Lens**
PRODUCTION METHOD	Lathing	Lathing
INTENDED USE	Daily Wear	Daily Wear
MATERIAL	Paflufocon D Center hem-iberfilcon A skirt	Synergicon-A
Type	Group 1 Low Water	Group 1 Low Water
Surface Charge	Non-ionic	Non-ionic
Color additive (Scientific name)	D&C Green 6	
UV additive	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: 9.1	RGP Center: FATT: 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	ISO: 17.5
Light transmittance: **(380nm to 780nm)**	>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

SEP 2 _ 2005

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: K051035
Trade/Device Name: SynergEyes™ (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: September 1, 2005
Received: September 1, 2005

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,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNERGEYES, INC. 510(k) Premarket Notification	SECTION 2 INDICATION FOR USE STATEMENT
SYNERGEYES (paflufocon D hem-iberfilcon A) HYBRID CONTACT LENS	DAILY WEAR CONTACT LENS

SECTION 2 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K051035/S001

Device Name: SynergEyes® A and M (paflufocon D hem-iberfilcon A) Hybrid Contact Lens

Indication for Use

SynergEyes® A and M (paflufocon 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 and +4.00D. 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 _____

Mary Watkins

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K051035/S001