NOV 3 0 2005

SynergEyes™, Inc.
Carlsbad, CA 92008

K052675

# 510(K) SUMMARY

**Applicant's Name and Address**

SynergEyes™, Inc.
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(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™ KC (paflufocon D hem-iberfilcon A) Hybrid Daily Wear Lens for Keratoconus |
| Classification: | Daily Wear Soft (hydrophobic) Contact Lens |
| Device classification: | Class II (21 CFR 886.5916) |

**2. Description of device**

The SynergEyes™ KC (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, -0.50 to -6.00D cylinder
- with center thickness from 0.18mm to 0.30mm
- with base curves of 5.50mm to 7.70mm
- with diameter of 14.50mm

The lens material (paflufocon D hem-iberfilcon A) is identical to the predicate current material cleared under K051035. 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 keratoconus: 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 used in keratoconus and manufactured by Ciba Vision Corporation.

The SynergEyes™ KC 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.

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**3. Intended use**

SynergEyes™ KC (paflufocon 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 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) was selected to address: material (silicone acrylate- paflufocon D) for the optic portion of the lens and (hem-iberfilcon 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 Hybrid (RGP-soft skirt concept)

| | | |
|---|---|---|
| SynergEyes™, Inc.<br>SoftPerm (synergicon A) Mixed use Lens | K051035<br>P840004/S7 | Cleared: Sep. 2, 2005<br>App: 10/14/1993 |

- For the RGP Center Portion:

| | | |
|---|---|---|
| Paragon Vision Sciences | P870024/S36 and S43<br>K940277 | App: 11/23/1993 and 4/13/2002<br>Cleared: 5/9/1994 |

- For the Soft Skirt Portion:

| | | |
|---|---|---|
| SynergEyes™, Inc.<br>SoftPerm (synergicon A) Mixed use lens | K051035<br>P840004/S7 | Cleared: 9/2/2005<br>App: 10/14/1993 |

**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™ K (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** | 5.50-7.70mm | 7.10-9.00mm | 7.10-8.10mm |
| **RGP Center** | 8.40mm | 8.40mm | 8.00mm |
| **Posterior Optic Zone** | 9.0mm | 7.80mm | 7.00mm |

| **Diameter** | | | |
|---|---|---|---|
| **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 | |
| **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 series of physical/chemical and toxicological tests were conducted under K051035 for the equivalent lens, the predicate lens for this device. All tests may be referenced to K051035 of the sponsor, SynergEyes, Inc.

Non-clinical studies included in K051035 and summarized here are:

- Chemistry and leachability: Residual monomer testing was conducted in accordance with Standardized protocols adopted by US and ISO standards. The results indicated that the residuals were of trace levels, and not toxic to test animals.

- Toxicology (cytotoxicity, Ocular Irritation, and Systemic Injection)- Testing was conducted on extracts of the hybrid lens material for all three biocompatibility tests and found to be non-toxic for each of the test protocols run on these materials.

- Solution Compatibility-Compatibility was demonstrated by subjecting10 lenses to a 30 cycle disinfection regimen with approved solutions. Results indicated that the subject lenses were compatible with lens solutions that are approved for both soft and RGP material.

- Microbiology/Sterilization: The finished lenses were subject to e-beam sterilization and found to be sterilized using standard USP protocol. Initial shelf life was established at one year. Extensions of shelf-life are subject to the same protocol which incorporates acceleration aging backed by real-time studies, and all subject to end time sterility verification.

**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 one month clinical study of the SynergEyes™ KC Hybrid Contact Lens was conducted to assess safety and effectiveness for vision correction in daily wear that included subjects with keratoconus and irregular astigmatism with refractive errors including myopia, hyperopia, and/or astigmatism. The purpose of the study was to profile the outcome endpoints and patient acceptance of the SynergEyes™ KC Hybrid Contact Lens for the conditions described herein. The primary outcomes for safety was adverse events and loss of visual acuity. The primary outcome for effectiveness was contact lens visual acuity by eye. Additional effectiveness outcomes included percentage of completed subjects and lens wearing time. The primary safety endpoints included visual acuity loss of greater than 2 lines of vision, assessment of serious adverse events, complications, and symptoms, problems, and complaints among others.

The study was designed as a prospective, multi-site, open label study with a 1 month aggregate lens wearing period for each completing subject. Subjects were enrolled at 12 sites and must have satisfied the patient inclusion and exclusion criteria specified in the protocol. Prior lens experience was recorded. Data were collected at baseline, dispensing and follow-up visits of 1 and 2 weeks, and 1 month.as well as unscheduled visits.

The population demographics were similar to previous contact lens studies with a female to male gender ratio of 1.48 to 1.0. The average age of the completed and discontinued subjects was 40.7 and 39.4 respectfully.

There were a total of 62 subjects who were dispensed and evaluated of which 44 (71%) subjects completed, and 18 (29%) subjects were discontinued.

The distribution of the reasons for discontinuation is enumerated below.

Figure 1

| Reason For Discontinuation | Over All Visits | |
|---|---|---|
| | # Subjects | % |
| Poor Comfort | 7 | 38.9% |
| Poor Outcome with Lenses | 3 | 16.7% |
| Other | 3 | 16.7% |
| Poor Vision | 2 | 11.1% |
| Non-Compliance | 2 | 11.1% |
| Loss of Interest | 1 | 5.6% |
| Total Subjects | 18 | |

The "Other" reasons for discontinuation included: "moving to Japan", "moved 4 hours away", and "lens ripping – too time consuming to restart".

The most frequent reasons cited for subject discontinuation were Poor Comfort (15 subjects, 32.6%) and Loss of Interest (13 subjects, 28.3%). Thirteen (13) of the 15 subjects discontinued for Poor Comfort exited the study within the first month of lens wear. One lens complication reported as 'Poor outcome with lenses' in one patient (2 eyes) with corneal abrasions was treated and resolved.

**Safety Assessment:**

Four (4) adverse events were reported during the study for 2 completed subjects and 2 discontinued subjects. . One subject presented with mechanical abrasion on the apex of the cone in both eyes after several lens dispensing visits, one subject experienced transient changes in intraocular pressures in both eyes at the 1 week follow-up visit, one subject presented with edema and infiltrates in the left eye 61 days after first lens dispensing, and one subject presented with a red left eye with small infiltrates 14 days after first lens dispensing.

The safety analysis was enhanced by slit lamp (biomicroscopic) examinations which were performed at each follow-up visit to evaluate the ocular surface to determine if there was evidence that the study lenses initiated or aggravated changes to the corneal surface. The results of the examinations show characteristics of subjects with keratoconus with relatively high rates of staining, injection, edema and neovascularization.

Staining was reported for 50.1% completed eyes, 52.0% for discontinued eyes of which 4.0% and 3.3% was reported respectfully for moderate (Gr. 3) staining. Injection was reported for 44.7% completed eyes and 42.3% for discontinued eyes of which 0.7% and 0.8% was reported respectfully for moderate (Gr. 3) injection. Neovascularization was reported for 22.6% completed eyes, and 14.6% discontinued eyes of which only 1 severe neovascularization (Gr. 4) was reported for a discontinued eye. The subject entered the study with the same degree of neovascularization. Finally, edema was reported for 4.0% completed eyes, and 15.4% for discontinued eyes of which no reports of moderate (Gr. 3) or severe (Gr. 4) findings were received.

The most common symptoms, problems, and complaints for completed eyes were cited as discomfort/awareness (26.0%), dryness/scratchiness (12.5%), blurred vision (11.7%), and itching/burning (10.6%). These rates were higher for discontinued patients (41.6%, 18.7%, 24.7%, and 13.9% respectfully.

**Efficacy Assessment:**

Visual Acuity- Final visual acuity for completed subjects was 20/20 or better (26.3%), 20/25 or better (55.1%), 20/30 (71.4%), and 20/40 or better (83.9%). The visual acuity rates for discontinued subjects were 8.4%, 27.8%, 47.2%, and 52.8% respectfully. Vision correction fluctuated as expected with the instability of the corneal curvature from keratoconus under the contact lens contributing to the change. Five (5) completed eyes and 3 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 11.4 hours per day.

**Conclusion:**

The SynergEyes™ KC Hybrid Contact Lens for Keratoconus 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™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™ KC Hybrid Contact Lens for Keratoconus** | **Jurkus (1998)** | **Chung (2001)** |
|---|---|---|---|
| **No. of Lenses (Eyes)** | 116 | 21 | 35 |
| **No. Patients** | 62 | 11 | 28 |
| **Gender** | 40F/27M | 5F/6M | 11F/17M |
| **Mean Age** | 40.7 (Completed) | | 41 + 19 |
| **Lens** | SynergEyes KC | Saturn II (SoftPerm) | SoftPerm/Prior RGP users |
| **Indication** | Myopia, Hyperopia, Irr. Astimgatism | Astigmatism | Keratoconus 22/35 (62.9%) and PK 10/35 (28.8%) |
| **Completions** | 44 (71%) | 4 (36%) | 17 (66.7%) |
| **Discontinuations** | 18 (29%) | 7 (64%) | 11 (33.3%) |
| **For Comfort** | 38.9% | 28% | 45.5% |
| **For Vision** | 11.1% | 28% | 9.1% |

**Material Equivalence Table**

| | **SynergEyes™ K Hybrid Contact Lens for Keratoconus**<br><br>**Subject Device** | **SynergEyes™ A and M Hybrid Contact Lens for Daily Wear**<br><br>**(K051035)** | **SoftPerm® Contact Lens**<br><br>**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 (Scientific name)** | D&C Green 6 | D&C Green 6 | |
| **UV additive** | No | No | No |
| **Dk permeability:**<br>**1. Revised FATT Polarimetric method with edge correction @ 35°C x $10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg)**<br><br>**2. ISO 9913-1** | RGP Center:<br>FATT: 145<br>ISO: 100<br>- - - - - - - - - - - - - - - - - -<br>Soft Skirt: 9.3 | RGP Center:<br>FATT: 145<br>ISO: 100<br>- - - - - - - - - - - - - - - - - -<br>Soft Skirt: 9.3 | RGP Center:<br>ISO: 14<br>- - - - - - - - - - - - - -<br>Soft Skirt: 5.5 |

| | | | |
|---|---|---|---|
| **Dk/L- Lens transmissibility:**<br>**1. Revised FATT (Through power range -20 to + 20D)**<br><br>**2. ISO 9913-1 Polarimetric method :** | FATT: 66-77<br>ISO: 46-53 | FATT: 66-77<br>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

NOV 3 0 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: K052675
Trade/Device Name: SynergEyes™ KC (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Keratoconus 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 23, 2005
Received: September 27, 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.<br><br>510(k) Premarket Notification | SECTION 3<br><br>INDICATION FOR USE STATEMENT |
|---|---|
| SYNERGEYES™ (paflufocon D hem-iberfilcon A) HYBRID CONTACT LENS FOR KERATOCONUS | DAILY WEAR CONTACT LENS |

## SECTION 2 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K052675

Device Name: SynergEyes™ KC (paflufocon D hem-iberfilcon A) Hybrid Contact Lens for Keratoconus

### Indication for Use

SynergEyes™ KC (paflufocon 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 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 _____

Karen Waburton

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K052675