MAY 18 2006

K060821

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): **SpecialEyes, LLC.**
P.O. Box 21417
Bradenton, FL 34204
Phone: 886-404-1060 Fax: 886-404-1030

Contact Person: Steve Brauner

Date of Summary: May 4, 2006

Trade/Proprietary Name: Special Eyes 59 and Special Eyes 49 Sphere and Toric Soft Contact Lenses

Classification Name: Lenses, soft contact, daily wear

Product Code: LPL

Intended Use:

The Special Eyes 59 (hioxifilcon A) Sphere and Toric soft contact lenses for daily wear, are indicated for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes with myopia or hypercopia, and/or posses refractive astigmatism not exceeding 10 diopters. They are available for either conventional wear or planned replacement modalities.

The Special Eyes 49 (hioxifilcon B) Sphere and Toric soft contact lenses for daily wear, are indicated for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes with myopia or hypercopia, and/or posses refractive astigmatism not exceeding 10 diopters. They are available for either conventional wear or planned replacement modalities.

Device Description:

SpecialEyes 59 and 49 soft contact lenses are hemispherical shells available in spherical or toric lens designs and in. hioxifilcon A and hioxifilcon B materials.The lenses are fabricated by lathe cutting hioxifilcon A and hioxifilcon B materials both non-ionic copolymers of 2-hydroxeyethylmethacrylate (2-HEMA) and Glycerol Methacrylate (GMA). The water content by weight is 49% for hioxifilcon B and 59% for hioxifilcon A. when immersed in normal saline. In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent optical surface.

Preclinical Testing:

Dimensional and verification testing has been completed and included in Section 10 of this submission. As evidenced in the results all product conformed to specification requirements. All other preclinical testing such as toxicology, microbiology, lens compatibility, preservation uptake tests and shelf life studies were completed on the predicate device, which is identical to the device proposed in this 510(k), see K964528.

Substantial Equivallence to Predicate Device:

SpecialEyes claims the proposed device to be substantially equivalent to the devices previously cleared by FDA as listed below. SpecialEyes claims this equivalence be cause the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational and biological specification as compared to the predicate devices.

The similarities and differences between the proposed and predicate devices have been identified and explained in the Comparison Matrix which has been included in Section 9 of this submission.

K983773 - BENZ G-5X (HIOXIFILCON A) SOFT DAILY WEAR CONTACT LENS
K964528 - BENZ-G 3X (HIOXIFILCON B) SPHERICAL AND TORIC SOFT DAILY WEAR CONTACT LENS
K042242 – ALDEN HP SHPERE AND TORIC / OXYLENS
K981252 - ALDEN HP SHPERE AND TORIC / OXYLENS
K953199 – METRO OPTICS SATUREYES SPHEREICAL AND TORIC
K964902 - METRO OPTICS SATUREYES SPHEREICAL AND TORIC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2006

SpecialEyes, LLC
c/o Mr. Arthur J. Ward
AJW Technololgy Consultant, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K060821
Trade/Device Name: SpecialEyes59 and SpecialEyes 49 Sphere and Toric soft contact lenes
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lenses
Regulatory Class: II
Product Code: LPL
Dated: May 4, 2006
Received: May 8, 2006

Dear Mr. Ward:

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.
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): K060821

Device Name: SpecialEyes 59 and SpecialEyes 49 Sphere and Toric soft contact lenses

Indications for Use:

The Special Eyes 59 (hioxifilcon A) Sphere and Toric soft contact lenses for daily wear, are indicated for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes with myopia or hypercopia, and/or posses refractive astigmatism not exceeding 10 diopters. They are available for either conventional wear or planned replacement modalities.

The Special Eyes 49 (hioxifilcon B) Sphere and Toric soft contact lenses for daily wear, are indicated for the correction of visual acuity in aphakic and non aphakic persons with non-diseased eyes with myopia or hypercopia, and/or posses refractive astigmatism not exceeding 10 diopters. They are available for either conventional wear or planned replacement modalities.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060821