DEC 2 6 2001

510(k) PREMARKET NOTIFICATION

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The Assigned 510(k) Number: **K013445**

Applicant Information

Date Prepared:	September 22, 2000
Name:	Florida Optical Engineering, Inc.(FLOE)
Registration Number:	_____
Address:	13709 Progress Boulevard, Box 14 Alachua, Florida 32615
Contact Person:	Richard A. Griffin, O.D., President
Phone Number:	(386) 418-4397
Fax Number:	(386) 418-4397
e-mail Address:	drrichardagriffin@alltel.net

Manufacturing and Sterilization

Euclid Systems Corporation
2810 Towerview Road
Herndon, VA 2017

Contact Person:	George E. Glady, VP Operations
Phone Number:	800-447-9396
E-mail Address:	George@Euclid.sys

Device Information

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Soft Contact Lenses, Daily Wear
Trade/Proprietary Name:	OSPREY™ Spherical (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses
and	
	OSPREY™ Toric (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses

The material, Benz-G 5X (hioxifilcon A), may be disinfected using a chemical (non-thermal) disinfection system.

3. <u>UltraVue/P and UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks)</u> is the predicate device because it is manufactured from:
   (a) the same polymer (hioxifilcon B), the polymer which already has FDA clearance,
   (b) using similar multifocal lens designs and
   (c) using lathe-cutting equipment.

   UltraVue/P and UltraVue/C (hioxifilcon B) soft contact lenses made from clear and a blue visibility tint BENZ-G 3X lens blanks are intended for daily wear for correction of visual acuity of aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The Lenses may be worn by people who may exhibit astigmatism of 0.75 Diopters or less where astigmatism does not interfere with visual acuity.

   The material, Benz-G 3X (hioxifilcon B), is non-ionic polymer that may be disinfected using either the heat (thermal) or chemical (non-thermal) disinfection system.

The physical properties of the lens blanks made from Benz-G 3X (hioxifilcon B) lens polymer material, which are used to manufacture predicate devices number 1 and 3 are listed in Table 4.

Table 4. Physicochemical Properties(*) of Benz-G 3X (hioxifilcon B) Lens Blanks Polymer Material.

Refractive Index	1.515 (dry) and 1.425 (hydrated)
Color Pigment Name	Phthalocyanine Blue
Light Transmission (Clear)	greater then 95% T
Light Transmission (Tinted)	greater then 95% T
Water Content	48% by weight
Specific Gravity	1.308 (dry) and 1.136 (hydrated
Oxygen Permeability	15×10^{-11} (cm^2/sec)(ml O_2/ml x mm Hg@35¡C) (revised Fatt Method)

(*) NOTE: Data Taken from Technical Manual, Benz Research and Development, Inc. (April 1999)

INTENDED USE

The **OSPREY Spherical (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia. The lenses may be worn by persons with astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The **OSPREY Toric (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia and astigmatism of 4.5 diopters or less.

Eye care practitioners may prescribe the lenses for planned replacement wear with cleaning, disinfection and scheduled replacement (See WEARING SCHEDULE). When prescribed for planned replacement wear, the lenses may be disinfected using either a heat or chemical disinfection system.

DESCRIPTION OF DEVICE

OSPREY™ Spherical or Toric (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks) are made from clear and a blue visibility tint BENZ-G 3X (hioxifilcon B) lens blanks intended for daily wear for correction of visual acuity of aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lenses are manufactured by lathe-cutting of lens blanks in dry (i.e. non-hydrated) state into hemispherical shell which can be polished when desired. The toric contact lens have a Toric Base Curve.

Osprey™ Multifocal Soft Contact Lens is a center-distance, simultaneous-focus, progressive-addition lens. Focal power within the central power zone is generated on the front surface, beginning at the central distance power, and increasing radially outward. Labeled Add Power is that Add Power which is occurring at the pupillary zone diameter of 3.5 mm. The back surface may be either spherical or toric for correcting astigmatism. The toric lens is held on axis by the superior and inferior front surface flanges, formed by slab-off. The lenses are available in clear and with a blue visibility tint as supplied by the manufacturer of lens blanks.

Side-by-side comparison of the key physical/chemical/optical properties of the ***Osprey™ Multifocal*** Contact Lens compared with the lenses to which substantial equivalence is sought is given in Table 5. As can be seen from this table, the Present Device, that is, *OSPREY™ Multifocal Soft Contact Lens* satisfies the requirements for substantial equivalency determination. Only difference is in the shape of lens curvature, which defines the optics, all other aspects are the same for this lens and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 26 2001

Richard Griffin, O.D.
Florida Optical Engineering, Inc. (FLOE)
13709 Progress Boulevard, Box 14
Alachua, FL 32615

Re: K013445
Trade/Device Name: Osprey (hioxifilcon B) Spherical and Toric Multifocal Lens for Daily Wear.
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft Contact Lens, Daily Wear
Regulatory Class: Class II
Product Code: LPL
Dated: October 17, 2001
Received: October 17, 2001

Dear Dr. Griffin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number: K013445

Device Name: **OSPREY™ Spherical or Toric (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks).**

Indications for Use:

The **OSPREY Spherical (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia. The lenses may be worn by persons with astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The **OSPREY Toric (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia and astigmatism of 4.5 diopters or less.

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

510(k) Number K013445

Prescription Use X
(Per 21 CFR 801.109)