DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FCI Ophthalmics, Inc.
c/o Hillard W. Welch
U.S. Representative for FCI
344 Annabelle Point Road
Centerville, MA 02632-2402

FEB 2 6 2003

Re: K030054
Trade/Device Name: Disposable Vitrectomy Lenses
Disposable Infusion Cannula
Surgical Knife
Regulation Number: 21 CFR 886.1385; 21 CFR 886.4350
Regulation Name: Polymethylmethacrylate (PMMA) diagnostic contact lens
Regulatory Class: Class II; Class I; Class I
Product Code: HJK; HMX; HNN
Dated: December 31, 2002
Received: January 6, 2003

Dear Mr. Welch:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K030054

Device Name: Disposable Vitrectomy Set
Disposable Vitrectomy Lenses

Indications for Use:

The disposable Vitrectomy Set is used in the context of vitrectomy procedures. The self-blocking infusion cannula with infusion tubing provides the saline solution or balanced saline solution throughout the procedure, ensuring that the eye retains its tonicity. No sutures are required. The knife is used for making a calibrated and non-leaking incision into which the self-blocking infusion cannula is inserted. The lens, used with microscope, facilitates visualization of the retina by canceling the corneal diopter. An edge, which has a frosted ring on its upper side to avoid edge glare effects, allows users to position and move the lens on the cornea with forceps.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David W. Brown, Ph.D.

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

510(k) Number K030054

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)