MAY 20 1998

K980636

510(k) Summary
Fiber Optic Endoillumination Probe
(per 21 CFR 807.92)

1. SUBMITTER NAME AND ADDRESS

DUTCH OPHTHALMIC, USA
One Little River Road
P.O. Box 9868
Kingston, NH 03848 USA

Contact Person: Mark W. Furlong, President
Telephone: 603-642-8468

Date Prepared: February 9, 1998

2. DEVICE NAME

Trade Name: Fiber Probe
Proprietary Name: Fiber Optic Endoillumination Probe
Classification name: Light, Surgical, Fiberoptic

3. PREDICATE DEVICE

Infinitech, Inc. Fiber Optic Probe (K870942)

4. DEVICE DESCRIPTION

The Fiber Optic Endoillumination Probe provides intraocular illumination. The light is transmitted from the source to the inside of the eye through a flexible optical fiber, which has been threaded through an illumination probe.

5. INTENDED USE

The Fiber Optic Endoillumination Probe is indicated for intraocular illumination in vitreoretinal surgery.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Operational and technological characteristics form the basis for the determination of substantial equivalence of the Fiber Optic Endoillumination Probe with legally marketed predicate devices. Information supplied in this premarket notification includes descriptive information about the intended use, operation, and technological characteristics.

COMPARISON TABLE

Comparison Criteria	**Dutch Ophthalmic, USA Fiber Optic Endoillumination Probe**	**Infinitech, Inc. Fiber Optic Probe**
Device Type: Fiber Optic Probe	Yes	Yes
Indication: Intraocular illumination in vitreoretinal surgery	Yes	Yes
Patient Contact Materials: PMMA and fluoropolymer fiber and medical grade Surgical stainless steel	Yes	Yes
Sterilization Method	Validated ETO	Not Known
Packaging	Validated Heat Sealed Tyvek	Not Known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Mr. Mark W. Furlong
President
Dutch Ophthalmic, USA
One Little River Road
P.O. Box 968
Kingston, New Hampshire 03848

Re: K980636
Trade Name: Fiber Optic Endoillumination Probe
Regulatory Class: II
Product Code: FFS
Dated: February 9, 1998
Received: February 19, 1998

Dear Mr. Furlong:

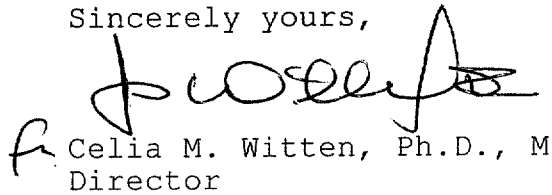
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980636

Device Name: Fiber Optic Endoillumination Probe

Indication For Use:

Fiber Optic Endoillumination Probe is indicated for intraocular illumination in vitreoretinal surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980636

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____