JUN 25 1997

Ophthalmic Technologies Inc.
37 Kodiak Crescent
Unit 16
Downsview, Ontario M3J 3E5
Canada
416-631-6932
Revised 6/16/96
510(k) Summary

1. Submitter Information

a. Name: Ophthalmic Technologies Inc.

b. Address:

Ophthalmic Technologies Inc.
30 Kodiak Crescent, Unit 16
Downsview, Ontario M3J 3E5, CANADA

c. Telephone Number: 416-631-6932

d. Contact Person: Dr. George Myers, 201-727-1703

e. Date Summary Prepared: March 31, 1997

2. Device Information

a. Trade or proprietary name: OTI i-scope ophthalmic endoscope.

b. Common name: Ophthalmic Endoscope

c. Classification name: Endoscope, Ophthalmic

3. Predicate Devices:

a. ElectroFiber Optics Fiber Optic Endoscope

b. EndoOptiks Microprobe

4. Description of the device

The Ophthalmic Technologies i-Scope™ is a rigid ophthalmic fiber-optic microendoscope. The i-Scope has an imaging fiber bundle with 10,000 pixels, an illumination fiber, and a working channel for an optional laser fiber or microinstruments. The laser fiber is disposable and can be

replaced between cases. The fiber is not manufactured by Ophthalmic Technologies. The image fiber bundle terminal is connected to an orientation ring, video adapter and video camera. The illuminating bundle fiber can be connected to the OTI "XE-LITE" Xenon Light Source, or other light sources which have been cleared by the FDA. The laser fiber is disposable and can be replaced between cases.

5. Intended Use

The Ophthalmic Technologies i-Scope™ is intended to be used for visualization of intra-ocular structures, as a means to introduce micro instruments into the eye, or as a means to introduce laser fibers for photocoagulation.

6. Technological Characteristics

a. Comparisons

The i-scope is comparable to the EndoOptiks Microprobe, an ophthalmic endoscope, and the ElectroFiber Optics Fiber Optic Endoscope, a general-purpose endoscope. Its intended use and specifcations are very close to that of the EndoOptiks device. Materials and construction are also similar to that used in the ElectroFiber Optics device.

b. Data

(1) Non-Clinical Tests presented:

(a) Resolution with test pattern

(b) Light output compared to other devices

(2) Clinical tests: Not required

(3) Materials: All materials used in this device have been used in predicate devices.

c. Conclusion:

The tests provided show that the OTI i-scope is as safe and effective, and perform as well as or better than the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

Ophthalmic Technologies, Inc.
c/o Dr. George Myers
Official Correspondent
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K971679
Trade Name: i-SCOPE Ophthalmic Endoscope
Regulatory Class: II
Product Code: 86 MPA
Dated: April 4, 1997
Received: May 7, 1997

Dear Dr. Myers:

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 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 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) 594-4613. 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" (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,

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

Enclosure

K971679

510(k) Number (if known):_____

Device Name: i-scope Ophthalmic Endoscope

Indications for Use:

The Ophthalmic Technologies i-Scope™ is intended to be used for visualization of intra-ocular structures, as a means to introduce micro instruments into the eye, or as a means to introduce laser fibers into the eye for photocoagulation.

(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 Ophthalmic Devices
510(k) Number K971679

Prescription Use ✓ **OR** **Over-the-Counter Use** ____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)