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Ophthalmic Technologies Inc.
510(k) Submission
Di-rhex Ophthalmic Diathermy System

510(k) Summary

(1) Submitter Information

Name: Ophthalmic Technologies Inc.

Address:

37 Kodiak Crescent
Downsview, Canada M3J 3E5

Telephone Number: 416-631-9123

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: January 6, 1999

(2) Name of Device

Trade Name: Di-rhex Ophthalmic Diathermy System
Common Name: Ophthalmic Diathermy System
Classification name: Radio Frequency, Electrosurgical, Cautery Apparatus

(3) Equivalent legally-marketed devices.

1. Dutch Ophthalmic USA system, "D.O.R.C. Microdiathermy System," K962135.
2. Surgitron Diathermy System, K980170

(4) Description

The system consists of a central control unit that supplies radio frequency energy to a handpiece. The unit can be used for standard diathermy procedures, and can be also used as a cutting instrument for membrane dissection in the eye with the appropriate

handpieces and tips. Power level is microprocessor-controlled, and the power-level setting is shown by a bar-graph display on the front panel. The system has a set of alarms which alert the user and suspend operation for such cases as overtemperature, overvoltage, and computer errors.

(5) Intended Use

The OTI Di-rhex Ophthalmic Diathermy Unit is intended to be used for producing haemeostasis in the anterior and posterior segment of the eye, for conjunctival welding (coaptation), retinal coagulation using endodiathermy tips, and for cutting in ophthalmic surgery, using a high frequency current applied by a bipolar probe.

(6) Performance Data

(a) Non-clinical tests

The Di-rhex has had power output tests that confirm the specifications.
The Di-rhex has a safety test from the Canadian Standards Association.
The system software has had extensive validation testing.

(b) Clinical tests

The Di-rhex has had a clinical evaluation in Canada.

(c) Conclusions

The OTI Di-rhex Ophthalmic Diathermy System is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 1999

Ophthalmic Technologies, Inc.
George H. Myers, Sc.D.
c/o Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, N.J. 07604

Re: K990064
Trade Name: Di-Rhex Ophthalmic Diathermy System
Regulatory Class: II
Product Code: 86 HQR
Dated: January 6, 1999
Received: January 8, 1999

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 (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 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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K990064

Indications for Use Form

Device Name: Ophthalmic Technologies Di-rhex Ophthalmic Diathermy System

Indications for Use:

The OTI Di-rhex Ophthalmic Diathermy Unit is intended to be used for producing haemeostasis in the anterior and posterior segment of the eye, for conjunctival welding (coaptation), retinal coagulation using endodiathermy tips, and for cutting in ophthalmic surgery, using a high frequency current applied by a bipolar probe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwyn R Hoang, Scientific Reviewer
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990064

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

(Optional Format 1-2-96)