NOV 2 2 2004

ENDO OPTIKS

K042918 1/3

39 Sycamore Ave.
Little Silver, NJ 07739
Tel: 732 530 6762 Fax: 732 530 5344

Attachment 11

510(k) Summary
For the E2 MicroProbe

.1 - Date Summary Prepared

October 18, 2004

2. - Submitter's Name and Address

Endo Optiks, Inc.
39 Sycamore Avenue
Little Silver, NJ 07739-1208
Contact Person: Keith Hertz

Tel.: 732-530-6762 Fax: 732-530-5344

E-mail: info@endo-optiks.com
khertz@monmouth.com

3. - Device Name

Trade / Proprietary Name: E2 MicroProbe Laser and Endoscopy System

Common Name: Various Laser and Endoscopy Systems

Classification Name: Laser, Ophthalmic

ENDO OPTIKS

K042918 2/3

39 Sycamore Ave.
Little Silver, NJ 07739
Tel: 732 530 6762 Fax: 732 530 5344

510(k) Summary
For the E2 MicroProbe

4. - Predicate Devices

The legally marketed device to which equivalence is being claimed is:

Uram Ophthalmic Laser Endoscope – MicroProbe

5. - Device Description

The Endo Optiks E2 MicroProbe™ is the principal component in a new portable laser and endoscopy system. The complete system consists of the therapeutic laser, the endoscope, the monitor and the footswitch. This compact unit creates the opportunity to simultaneously image and photocoagulate the ciliary processes through a corneal incision. It is especially indicated for the safe and effective treatment of glaucoma in combination with cataract surgery. Important vitreo-retinal applications can be realized. It can be used for the contact and non-contact excision, hemostatis, incision and vaporization of soft tissue. The E2 MicroProbe is a modification to the packaging of the original MicroProbe.

Labeling: The MicroProbe will be renamed (relabeled) the E2 MicroProbe. (Please see labels on Pages 2 & 3 of Attachment 1).

K042918 3/3

39 Sycamore Ave.
Little Silver, NJ 07739
Tel: 732 530 6762 Fax: 732 530 5344

510(k) Summary
For the E2 MicroProbe

Indications For Use:
Ocular Endoscopy
Cylophophotocoagulation for glaucoma
Photocoagulation of the Retina

6. - Intended Use
The E2 MicroProbe's intended use is for video imaging, illumination and photocoagulation using up to 1.2 watt of continuous wave radiation for endoscopic procedures. **This is the same intended use as the previously cleared ophthalmic laser endoscope, K910532.**

7. - Comparison of Technological Characteristics
This modification replaces the original MicroProbe with the E2 MicroProbe. The E2 MicroProbe has a different model of laser diode and has been repackaged without the video monitor in a smaller, streamlined cabinet. It has also been tested and found to be in conformity with recognized standards.

8. - Nonclinical Tests Used in Determination of Substantial Equivalence
The design of the E2 MicroProbe has been thoroughly validated at the unit and system level. The tests showed that all system specifications are satisfied.

9. - Conclusions From Nonclinical Testing
The testing of the modified device demonstrates that the performance is substantially equivalent to the predicate device.

Keith Hertz
Signature, Keith Hertz

10-18-2004
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Mr. Keith Hertz
Regulatory Affairs
Endo Optiks, Inc.
39 Sycamore Avenue
Little Silver, New Jersey 07739

Re: K042918
Trade/Device Name: E2 Microprobe Laser and Endoscopy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 18, 2004
Received: October 27, 2004

Dear Mr. Hertz:

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.

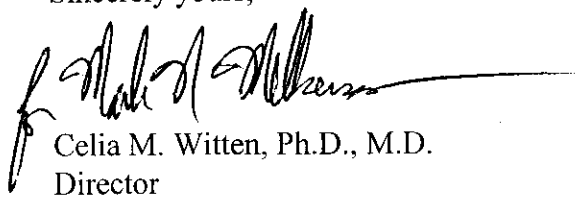
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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,



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

Enclosure

Indications for Use

510(k) Number : K042918

Device Name: E2 MicroProbe laser and endoscopy system.

Indications for Use:

The ophthalmic laser endoscope is indicated for intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do allow a posterior view.

Glaucoma

This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures.
The endophotocoagulation of ciliary processes under direct endoscopic view is highly controllable, i.e. titratable, and has been demonstrated to be effective in the treatment of glaucoma.

Vitreoretinal Surgery

The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation:

- During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites
- To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies
- To perform intraoperative retinal photocoagulation on a scleral buckle to perform intraoperative photocoagulation around focal neovascularization

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042918