MARTIN URAM, M.D.
Disorders of the Retina

39 Sycamore Avenue
Little Silver, New Jersey 07739
(908) 530-7730
Fax (908) 530-5344

225 East 64th Street
New York, New York 10021
(212) 628-0032

K974878

MAR 27 1998

510 (k) Summary For the E3 MicroProbe

1. - Date Summary Prepared:

December 15, 1997

2. - Submitter's Name and Address:

Martin Uram, MD

39 Sycamore Avenue

Little Silver, NJ 07739-1208

Contact Person: Keith Hertz

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

E-mail: mail@monmouth.com

3. - Device Name:

Trade / Proprietary Name: E3 MicroProbe

Common Name: Integrated Surgical Laser and Endoscope System

Classification Name: Surgical Diode Laser Fiber Optic Endoscope

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4. - Predicate Devices:

The legally marketed devices to which equivalence is being claimed are:

MicroProbe

Family of Endoscopes

Value Pack

Endoscope w. Cannula

Transtympanic Endoscope

Diomed (15, 30, 60)
Surgical Diode Laser

Coherent Surgical Laser

ASI Uroplasty Cystoscope

Olympus Arthroscopy System

Olympus Laparo-Thoraco Videoscope

Olympus Oratracheal Intubation Endoscope

Olympus Endoscope System

Pentax Video Colonoscope

Pentex Video Duodenoscope

Pentax Video Gastroscope

Pentax Video Sigmoidoscope

Pentax Bronchofiberscope

Storz Flexible Fiberscope

Storz Flexible Rhino-Pharyngo-Laryngo-Fiberscope

Storz Flexible Hysteroscope

Storz Hopkins Telescope

Stryker Arthroscopy System

Stryker Sinuscope

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5. - Device Description:

The Endo Optiks E3 MicroProbe System consists of a laser, endoscope, console and footpedal. The treatment laser is a solid state diode laser system operating at 810 nanometers ± 2 nanometers and continuous wave power of up to 60 Watts. A visible solid state diode laser operating at a nominal wavelength of 640 nm and a variable continuous wave output from 0 to 1.5 milliwatts is incorporated as an aiming device. The end of the endoscope consists of a 0.25 milimeter diameter fiberoptic for viewing, a 0.10 millimeter diameter fiberoptic for delivery of the laser energy and fiberoptics that transmit the illumination light. Laser energy is delivered via a single timed continuous wave pulse with the time preset at the operator console and the pulse initiated by the footpedal. Laser power is also preset at the console.

The E3 MicroProbe is a modification to the maximum power output rating of the original MicroProbe.

Labeling: The MicroProbe will be renamed (relabeled) the E3 MicroProbe. This change is being made to be consistant with the industry practice of designating a laser's power based on the output power at the laser port rather than that at the tissue site. There is no change in construction or performance of this device.

Power Output: An additional model will be created by increasing the output power to produce the E3 MicroProbe. The same basic design is retained. The 60 Watt model uses sixteen 4 Watt laser diodes. The power supply and cooling designs of the new model have been appropriately scaled, while the mechanical design and user interface remain unchanged.

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737

510 (k) Summary For the E3 MicroProbe

Indication For Use: The indications are expanded to include both contact and non-contact ablation, incision, excision, coagulation and vaporization for the following soft tissue applications:

- General Surgery
- Ophthalalmology / Oculoplastic
- Urology
- Gastroenterology
- Gynecology
- Otorhinolaryngology
- Pulmonary / Thoracic
- Dermatology / Plastic Surgery
- Neurosurgery
- Orthopedic

6. - Intended Use:

The E3 MicroProbe delivers up to 60 Watts of continuous wave radiation to a flexible optical fiber for use in open and endoscopic procedures.

7. - Comparison of Technological Charateristics

This modification replaces the original MicroProbe with four models, the Full Featured MicroProbe, the E3 MicroProbe - 15, the E3 MicroProbe - 30 and the E3 MicroProbe - 60. Modifications are to offer models with different maximum output powers (15, 30 and 60 Watts at the output port), in order to provide sufficient power when it is required, and to provide a more cost effective device for applications that do not require the higher power capabilities. The original MicroProbe currently operates with a maximum power of 15 Watts. In addition, indications for use have been expanded to include both contact and non-contact treatment of soft tissue applications for which legally marketed lasers are currently available.

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510 (k) Summary
For the E3 MicroProbe

8. - Nonclinical Tests Used in Determination of Substancial Equivalence

The design of the E3 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 devices demonstrates that the performance is substantially equivalent to the predicate prior to the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K974878
Trade Name: E3 MicroProbe Series of Diode Lasers and Accessories
Regulatory Class: II
Product Code: GEX
Dated: December 22, 1997
Received: December 30, 1997

Dear Dr. Uram:

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,

for 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

K974878 /12

DUPLICATE

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510(k) Number: K974878

Device Name: E3 MicroProbe

Indications For Use

Contact and non-contact excision, hemostasis, incision and vaporization for the following soft tissue applications:

General Surgery	**Otorhinolaryngology**
Ophthalmology / Oculoplastic	**Pulmonary / Thoracic**
Urology	**Dermatology / Plastic Surgery**
Gastroenterology	**Neurosurgery**
Gynecology	**Orthopedic**

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The-Counter-Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974878