K063828

DIOMED

JAN 25 2007

510(k) Summary of Safety and Effectiveness for the Diomed Delta 25 Laser

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	Diomed, Ltd. Building 2000 Beach Drive Cambridge Research Park Waterbeach Cambridge CB5 9TE United Kingdom
Contact Person:	Timothy G Phipps Address as above Telephone: +44 1223 729314 Fax: +44 1223 729329
Summary Preparation Date:	December 20th, 2006

2. Names

Device Name:	Diomed Delta 25 Laser
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. Predicate Devices

The Diomed Delta 25 Laser is substantially equivalent in terms of its technological performance to:

- Diomed Delta 15 and Diomed Delta 30 (K051996)

The Diomed Delta 25 Laser is substantially equivalent in terms of its laser wavelength performance to:

- Adept 1064 Laser (K032218)
- Sciton Inc. Profile 1064 Laser System (K023881)
- Laserscope Lyra Surgical laser System (K020021)
- Spectrum Veinlase (K981952)

4. Device Description

The purpose of this Special 510(k) is to notify FDA of the proposed inclusion of the Diomed Delta 25 Laser into Diomed's range of laser platforms.
The Diomed Delta 25 Laser consists of a Class IV InGaAs/AlGaAs laser diode with a wavelength of 1064nm ± 20 nm and a visible laser (aiming beam) of 5 milliwatt Class IIIa diode laser with a wavelength of 635 – 655 nm.

The Diomed Delta 25 Laser is made up of a treatment laser and aiming beam. The Diomed Delta 25 is a diode laser capable of delivering up to 25 W of continuous wave or pulsed radiation via an optical fiber coupled to the laser aperture. Drawings and photographs of the Diomed Delta 25 Laser are included in the operator manual found in **Appendix G.**

5. Indications for Use

The Diomed Delta 25 Laser is intended for use in delivering up to 25 Watts of continuous wave or pulsed radiation to a flexible optical fiber for use in ablation, incision, excision, coagulation and vaporisation of soft tissues in open and endoscopic surgical procedures.

6. Performance Data

The Diomed Delta 25 laser has undergone a comprehensive series of test protocols in order to qualify and validate the performance of the device. The results of the qualification/validation demonstrates equivalent performance to the predicate devices which themselves have substantial clinical and market evidence of acceptable performance. The Diomed Delta 25 is therefore validated for use on this basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Diomed Ltd.
% Mr. Tim Phipps
QA/RA Director
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Cambridge Research Park
Waterbeach
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JAN 25 2007

Re: K063828
Trade/Device Name: Diomed Delta 25
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: December 20, 2006
Received: December 26, 2006

Dear Mr. Phipps:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DIOMED

Indications for Use

510(k) Number (if known): K 063828

Device Name: Diomed Delta 25

Indications For Use:

Ablation, incision, excision, coagulation and vaporisation of soft tissues in the following open and endoscopic surgical procedures:

- General Surgery
- Ophthalmology/Oculoplastic
- Urology
- Gastroenterology
- Gynecology
- Otorhinolaryngology
- Pulmonary/Thoracic
- Dermatology/Plastic Surgery
- Neurosurgery (coagulation only)
- Orthopedic

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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
and Neurological Devices

510(k) Number K063828