NOV 1 6 2001

K013499

510(k) Summary for Diomed 15plus and Diomed 30plus Lasers

1. SPONSOR

Diomed Inc.
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MA01810
USA

Contact Person: Angie Glover
Telephone: 011 44 1223 729 337

Date Prepared: October 19, 2001

2. DEVICE NAME

Proprietary Name: Diomed 15plus and Diomed 30plus Lasers
Common/Usual Name: Surgical Lasers
Classification Name: Laser Surgical Instruments

3. PREDICATE DEVICES

Diomed 15 and Diomed 30 Lasers –K962354

4. DEVICE DESCRIPTION

The Diomed 15plus and Diomed 30plus Lasers are modified versions of the Diomed 15 and Diomed 30 lasers. A shorter pulse duration (50 ms) has been added to both the 15plus and 30plus lasers. The modified devices include a spot handpiece/software delivery system in addition to a fiber delivery system.

A Fluence Display has been added to enhance the efficiency of existing clinical indications when using the spot hand piece. A power meter (currently used in the

Diomed 30 laser) has been added to the Diomed 15plus laser to improve the accuracy of delivered power/fluence to the treatment site.

5. INTENDED USE

The Diomed 15plus and 30plus Lasers are intended for use in delivering 15 or 30 watts of continuous wave radiation to a flexible optical fiber or spot hand piece for use in ablation, incision, excision, coagulation, and vaporization of soft tissues in open and endoscopic surgical procedures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Diomed 15plus and Diomed 30plus Lasers and the original Diomed 15 and Diomed 30 Lasers all consist of a Class IV Gallium Aluminum Arsenide diode laser and a visible aiming beam. The original Diomed 15 and Diomed 30 lasers offer a fiberoptic mode while the modified Diomed 15plus and Diomed 30plus offers both a fiberoptic and spot handpiece mode.

The Diomed 15plus and Diomed 30plus Lasers and the Diomed 15 and Diomed 30 Lasers all have essentially identical performance characteristics except for slight changes to the pulse duration. Both the Diomed 15plus and Diomed 30plus lasers and the predicate devices offer a fiberoptic mode. Additionally, the proposed device offers a spot mode.

7. PERFORMANCE TESTING

Verification and validation testing was successfully performed to confirm that the modified Diomed 15plus and Diomed 30plus Lasers function as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Diomed, Inc.
c/o Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

NOV 1 6 2001

Re: K013499
Trade/Device Name: Diomed 15plus and Diomed 30plus Lasers
Regulation Number: 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 19, 2001
Received: October 22, 2001

Dear Ms. McNamara-Cullinane:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker, MD

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

510(k) Number (if known): K013499

Device Name: Diomed 15plus and Diomed 30plus Lasers

NOV 16 2001

Indications For Use:

The Diomed 15plus and Diomed 30plus lasers are indicated for contact and non-contact use for the following soft tissue applications:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Wall

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

510(k) Number K013499

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)