K062071

5.

510(k) Summary
of Safety and Effectiveness Information

SEP 28 2006

Company:

Spectrum International, Inc.
2643 Pleasant Hill Road
Pleasant Hill, CA 94523
Phone / fax: (925)798-8913

Contact Person:

George I. Bekov, President
Phone: (925)768-1122, fax: (925)798-8913

Preparation Date: July 17, 2006

Device Name:

- Trade name: PROMETEY ™
- Common name: Soft tissue diode laser
- Classification name: Laser instrument, Surgical, Powered
- Product code: GEX

Legally Marketed Predicate Devices for Substantial Equivalence:

-	K050453	Odyssey 2.4G	by Ivoclar Vivodent, Inc.
-	K030539	LaserSmile	by BioLase Technology, Inc.
-	K021227	SoftLase	by ZAP Lasers, LLC

Description of Submitted Device:

The *PROMETEY ™* diode laser system is a device for delivering laser power to treated surfaces within oral cavity. This power is produced by solid-state laser diodes, which provide a consistent generation of laser power in 810 ± 10 nm spectral region with maximum power of 3 Watts. The laser power is delivered to the treatment site by means of fiber optic cables available in 400, 300 and 200 μm core diameters. These cables provide safe transmission of laser power to the surgical site without creating undue risk to a patient or operatory staff by errant or collateral laser emissions. The device features front-panel keypad used to activate 650 nm aiming beam, set power output and select continuous or pulsed operation mode.

The distal end of delivery fiber cable is contained within a metal handpiece with a disposable tip /cannula. A standard foot-switch controls initiation /termination of laser power from the delivery fiber.

Intended Use of PROMETEY Soft Tissue Diode Laser:

The device is intended to be used for a variety of surgical procedures in the oral cavity:

Dental Soft Tissue Indications for incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:
Excision and Incision Biopsies, Hemostasis and Coagulation, Treatment of canker sores, herpetic and aphthous ulcers, Frenectomy and Frenotomy, Gingival Incision and Excision,

Gingivectomy and Gingivoplasty, Incision and Drainage of Abscess, Operculectomy, Oral Papillectomy, Removal of Fibromas and Hyperplastic tissues, Exposure of un-erupted / partially erupted teeth, Implant recovery, Tissue retraction / troughing, Leukoplakia, Pulpotomy, Soft tissue crown lengthening, Vestibuloplasty.

Laser Periodontal Procedures, including:
Laser soft tissue curettage, Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium, Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

Teeth Whitening Procedures, including:
Light Activation of bleaching materials for teeth whitening, Laser-assisted whitening / bleaching of teeth.

Technological Characteristics of Submitted and Predicate Diode Lasers and Substantial Equivalence:

Comparison Table

Feature	**Prometey**	**Odyssey 2.4G**	**LaserSmile**	**SoftLase**
510(k) Number	This application	K050453	K030539	K021227
Wavelength	810 ± 10 nm	810 ± 20 nm	810 nm	808 ± 5 nm
Max Power	3 Watts	5 Watts	10 Watts	3.5 Watts
Operation mode	Continuous wave and pulsed	Continuous wave and pulsed	Continuous wave and pulsed	Continuous wave and pulsed
Pulse control	Digital emission control	Digital emission control	Digital emission control	Digital emission control
Laser power source	Solid-state diode	Solid-state diode	Solid-state diode	Solid-state diode
Aiming beam laser	630-650 nm, 2 mW	630-650 nm, 3 mW	630-670 nm, 5 mW	650nm, 5 mW
Delivery system	Multi-mode fiber 400, 300, 200 um	Multi-mode fiber 400 um	Multi-mode fiber 1000-300 um	Multi-mode fiber 600, 400 um
Power requirements	100-240 VAC, 50-60Hz, 0.5 A	100-240 VAC, 50-60Hz, 1.5 A	100-240 VAC, 50-60Hz, 1.5 A	100-240 VAC, 50-60Hz, 1.0 A
Cooling system	Fan / air cooled	Fan / air cooled	Fan / air cooled	Fan / air cooled

The aforementioned diode laser devices and their delivery systems share similar indications for use in oral environment, similar design features including wavelength, operating controls, and laser power delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications except for maximum power output, which is the lowest for *Prometey* laser but is still enough to perform all Indications for Use since their laser power requirements are below 3 Watts.

Summary Basis of Equivalence:

There are no unique applications, indications for use, materials or specifications presented herein. Evidence of substantial equivalence has been demonstrated through:

- The *PROMETEY* ™ intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of *Prometey* diode laser are similar to those of cleared Odyssey 2.4G, LaserSmile and SoftLase diode laser systems.
- Laser power output values of *Prometey* are well within previously cleared values of predicate dental laser systems as described.
- The predicate devices and other previously FDA cleared diode laser systems with similar power outputs have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the *PROMETEY* ™ soft tissue diode laser system is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues. The device is designed to fully comply with relevant federal and international safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 2006

Spectrum International, Inc.
% Mr. George I. Bekov
President
2643 Pleasant Hill Road
Pleasant Hill, California 94523

Re: K062071
Trade/Device Name: PROMETEY™
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: July 17, 2006
Received: July 24, 2006

Dear Mr. Bekov:

This letter corrects our substantially equivalent letter of September 28, 2006.

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 (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 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 continue 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

4. Indications for Use

510(k) Number (if known): K062071

Device Name: PROMETEY ™

Indications for Use:

Dental Soft Tissue Indications for incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:
Excision and Incision Biopsies, Hemostasis and Coagulation, Treatment of canker sores, herpetic and aphthous ulcers, Frenectomy and Frenotomy, Gingival Incision and Excision, Gingivectomy and Gingivoplasty, Incision and Drainage of Abscess, Operculectomy, Oral Papillectomy, Removal of Fibromas and Hyperplastic tissues, Exposure of un-erupted / partially erupted teeth, Implant recovery, Tissue retraction / troughing, Leukoplakia, Pulpotomy, Soft tissue crown lengthening, Vestibuloplasty.

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Prescription Use ___X____ and /or Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K062071