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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

GENERAL INFORMATION

SEP 10 2010

Trade Name	*stLase*™
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	GEX
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	K081015: Biolitec Ceralas D980 K072262: KaVo GENTLEray 980 K982629: Dornier Medilase D Laser
Submitter/ Contacts	Marcy Moore MMP Medical Associates, LLC 16 Appleton St. Waltham, MA 02453 Phone: 919-363-2432 Fax: 919-363-0085

DEVICE DESCRIPTION

The Dental Photonics *stLase*™ is a 980 nm wavelength diode laser intended for use in general surgical applications and dental laser applications.

INTENDED USE

The *stLase*™ with surgical laser operation that can be used in contact or non-contact technique is intended for use in general surgery for incision/excision, vaporization, ablation and coagulation of soft tissue, and

The *stLase*™ with dental laser operation that can be used in contact or non-contact technique is intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment

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of aphthous ulcers, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy, and light activation of bleaching materials for teeth whitening.

PERFORMANCE DATA

Substantial equivalence of the *stLase*™ is demonstrated by similarity in technical specifications to the predicate devices. As a laser device, the *stLase*™ complies with 21 CFR 1040.10 and 1040.11 and other applicable laser and electrical safety standards.

SUBSTANTIAL EQUIVALENCE

The *stLase*™ has the same intended use, material design and function as predicate devices for dental laser applications: Biolitec Ceralas D980 family of lasers K081015; the Kavo GentleRay 980, K072262; and the same intended use, material design and function as the predicate device for general surgery laser applications: Dornier Medilas D family of lasers, K982629.

SUMMARY PREPARATION DATE: 8/23/2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dental Photonics, Inc.
% MMP Medical Associates, LLC
Ms. Marcy Moore
16 Appleton Street
Waltham, Massachusetts 02453

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Re: K094049
Trade/Device Name: stLase™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 24, 2010
Received: August 25, 2010

Dear Ms. Moore:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K094049 Pg 1 of 1

Device Name: *stLase*™

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Indications for Use:

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094049