

Submitter:

THE YOSHIDA DENTAL MFG. CO., LTD

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Contact: Hidenori Watanabe, Regulatory Affairs, hi-watanabe@yoshida-net.co.jp

Date Prepared: March 15, 2012

DEC 7 2012

1. Identification of the Device:

Proprietary-Trade Name: OPELASER PRO II and OPELASER Lite II

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology. Product Code GEX

Common/Usual Name: Powered laser surgical instrument

2. Equivalent legally marketed devices: K031440, DEKA, Model Smart US 20D; K030147

Lumenis Model: UltraPulse SurgiTouch

3. Description of the Device: These are CO² Laser devices designed for surgical applications. The

maximum power output for the PRO model is 7 watts, and for the LITE model, 5 watts. Type of laser is a CO² gas laser (class 4); Oscillation system: RF discharge excitation oscillation; Light guiding system: SiO² hollow fiber or 6 point articulated arm depending on model; Oscillation wavelength: 10.6µm.

4. Indications for Use. The Opelaser Family is CO₂ Medical Laser Systems (and the delivery system that are used to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

5. Safety and Effectiveness, comparison to predicate device. This device has the same indications for use as the predicate device and employs nearly identical technology to accomplish the same task. Delivered energy levels and wavelengths are essentially the same.

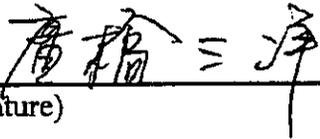
6. Description of Testing, nonclinical tests submitted: The OPELASER systems have undergone extensive safety and bench testing as well as software validation and risk analysis. The ability to sterilize the laser tips has been validated. The OPELASER systems have been tested and certified by the NRTL (Nationally Recognized Test Lab) Intertek. Certification to IEC/UL 60601-1 and IEC 60601-1-22 has been accomplished.

7. Substantial Equivalence: A detailed comparison of specifications and technologies, as well as comparisons of indications for use shows that the OPELASER device are substantially equivalent to the predicate devices. Safety standards applied are the same, as well.

8. Conclusion: The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 2, above.

Exhibit 6. Truthful and Accuracy Statement as required per 21CFR807.87(k).

I certify that, in my capacity as Executive Chief Operating Officer of the Laser division of The Yoshida Dental Mfg. Co., Ltd., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.



(Signature)

Mioki Hirohashi
Date: March 13, 2012



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

The Yoshida Dental Mfg. Co., Ltd.
% Kamm and Associates
Mr. Daniel Kamm
8870 Racello Court
Naples, Florida 34114

December 7, 2012

Re: K120932

Trade/Device Name: Opelaser Pro II and Opelaser Lite II
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: November 29, 2012
Received: December 03, 2012

Dear Mr. Kamm:

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,

Peter D. Rumm -S
2012.12.07 17:09:12 -05'00'

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120932

Device Name: OPELASER PRO II and OPELASER Lite II

Indications For Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)

Neil R Ogden
2012.12.07 16:46:19 -05'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number _____