November 3, 2021

Ivoclar Vivadent, Inc.
Donna Harnett
Director
175 Pineview Dr.
Amherst, New York 14228

Re: K050453
Trade/Device Name: Odyssey 2.4g, Denlaser Elite, Model 002-00050
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

Dear Donna Harnett:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 27, 2005. Specifically, FDA is updating this SE Letter as an administrative correction. A second product code was inadvertently included.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6276, Michael.Adjodha@fda.hhs.gov.

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director for Restorative and Surgical Dental Devices
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Ms. Donna Marie Hartnett
Director of QA/ Regulatory Affairs and Assistant Corporate Counsel
Ivoclar Vivadent Incorporated
175 Pineview Drive
Amherst, New York 14228

Re: K050453
Trade/Device Name: ODYSSEY 2.4G DIODE LASER
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, LYB
Dated: February 15, 2005
Received: February 22, 2005

Dear Ms. Hartnett:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050453

Device Name: ODYSSEY 2.4G DIODE LASER
Indications For Use:

Dental Soft Tissue Indications:

Dental, oral and soft tissue surgery including:

- Sulcular debridement of diseased or fibrous tissue
- Excision and biopsy
- Gingivectomy and gingivoplasty
- Lesion (tumor) removal
- Fibroma removal
- Tissue retraction (troughing)
- Aphthous ulcers
- Gingival hyperplasia (excision and recontour)
- Crown Lengthening
- Operculectomy
- Frenectomy
- Photocoagulation

Laser Periodontal procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

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)

[illegible] Restorative
[illegible] Devices

K050453

MAY 2 7 2005

510(k)

Summary of Safety and Effectiveness

Ivoclar Vivadent, Inc.
175 Pineview Dr., Amherst, NY 14228
Tel: 716-691-0010 Fax: 716-691-2294

Donna Hartnett, Director of QA/Regulatory Affairs
Preparation Date: May 16, 2005

Device Name:

Trade Name: Odyssey™ *2.4G Diode Laser*

Common Name: 810nm Diode Laser

Product Classification: Laser Instrument, Surgical, Powered

Legally Marketed Predicate Devices for Substantial Equivalence:

LaserSmile, Manufactured by BioLase Technology, Inc. (K030539)

DenLaser 800, Manufactured by CAO Group, Inc. (K003541)

Opus 10 Dental Diode Laser, Manufactured by OpusDent, Inc. (K000990)

Aurora SL Diode Laser, Manufactured by Premier Laser Systems, Inc. (K993285).

Rationale for Substantial Equivalence:

The aforementioned laser devices and their accompanying delivery systems share similar indications for use in the oral environment, similar design features including wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output and energy type.

Description of Submitted Device:

The Odyssey 2.4G Diode Laser is a device for delivering laser energy to surfaces within the oral cavity. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 5 watts of energy output. The laser energy is delivered to the surgical site by means of a proprietary optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 650nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is provided with the device. Activation of the working beam diodes is completed by use of a foot-activated switch.

Intended Uses of the Odyssey 2.4G Diode Laser:

The device is intended to be used for a variety of surgical procedures on soft tissue within the oral cavity.

Dental Soft Tissue Indications:

- Sulcular debridement of diseased or fibrous tissue
- Excision and biopsy
- Gingivectomy and gingivoplasty
- Lesion (tumor) removal
- Fibroma removal
- Tissue retraction (troughing)
- Aphthous ulcers
- Gingival hyperplasia (excision and recontour)
- Crown Lengthening
- Operculectomy
- Frenectomy
- Photocoagulation

Laser Periodontal procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium,

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Technological Characteristics and Substantial Equivalence:

The DenLaser 800 uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 630nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission. The maximum output of the unit 5 watts.

The Opus 10 Diode Laser uses solid-state diodes to generate laser energy in the infrared region. The system features timing controls that allows for variation in duration or intervals of laser emissions. This system also features a 630-650nm aiming beam.

The Aurora Laser System uses solid-state diodes to generate laser energy in the infrared region. This system features similar power output, spot size, and equivalent pulse duration to that of the submitted device.

The LaserSmile System uses solid state diodes to generate laser energy in the infrared region. The system features similar power output to that of the submitted device.

Performance Standards:

The Odyssey 2.4G Diode Laser complies with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with IEC 60601-1:1998+A1, IEC 60601-2-22:1995, and IEC 60825-1:1993+A1+A2. The device also complies with FCC regulations Part 15 for wireless devices.

PERFORMANCE DATA - Comparison Table

	Ivoclar Vivadent, Inc. Odyssey 2.4G Diode Laser	CAO Group, Inc. DenLaser 800	OpusDent, Inc. Opus 10 Dental Diode Laser	Premier Laser Systems, Inc. Aurora SL Diode Laser	LaserSmile Diode Laser Biolase Technology, Inc.
Wavelength	810±20 nm	810±20 nm	810 nm	810 nm	810nm
Power	5 watts	5 watts	10 watts	Unavailable	10 watte
Aiming Beam	630-650 nm, 3mW	630-650 nm, 3mW	630-680 nm, power unavailable	630-680 nm, power unavailable	630-670 nm
Cooling System	Fan air cooled	Fan air cooled	Fan air cooled	Fan air cooled	Fan air cooled
Pulse Control	Digital emission control	Digital emission control	Digital emission control	Digital emission control	20 ms-9.9 sec
Laser Source	Solid-state diode	Solid-state diode	Solid-state diode	Solid-state diode	Solid-state diode
Power Requirements	100-240 VAC @ 50-60 Hz, 1.5A (switchable)	100-240 VAC @ 50-60 Hz, 1.5A (switchable)	110-120VAC @ 50-60 Hz, 2.0A or 220-240VAC @ 50-60 Hz, 1.2A	115VAC @ 50-60 Hz, 0.8A Info on 220VAC unavailable	Not available
Dimensions	10" x 8" x 4"	10" x 8" x 4"	unavailable	12" x 12" x 6"	8.5" x 9" x 12.5"
510(k) Number	Pending this application	K003541	K000990	K993285	K030539

Conclusion

The Odyssey 2.4G Diode Laser is substantially equivalent to the listed laser surgical devices without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.