MAR 16 2007

K063384

510k Summary

Submitter: Hoya ConBio, Inc.
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Contact: Liza Burns
Regulatory Consultant

Date Summary Prepared: November 7, 2006

Device Trade Name: DioDent Micro 810 Dental Laser System
DioDent Micro 980 Dental Laser System

Common Name: Dental Diode Laser

Classification Name: Instrument, surgical, powered, laser
79-GEX

Classification Code: 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.
(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

Equivalent Device: SIROLaser by Sirona Dental Systems, K053161
DioDent II Dental Laser System by HOYA ConBio, K050274
Twilight Diode Laser System by BioLase Technologies, K991994

Device Description: The laser source of the DioDent Micro 810/980 is a solid-state Gallium Aluminum Arsenide (GaAlAs) semiconductor diode. It produces invisible laser energy at the 810-nanometer or 980nm wavelength. The delivery system consists of an autoclavable flexible treatment fiber threaded through a lightweight, autoclavable hand piece. Activation occurs when the operator enables the laser and presses the footswitch. Releasing the footswitch suspends laser treatment. The footswitch can function as an on/off switch. A color touch-screen display panel allows the operator to adjust or set laser output level with minimal effort.

	The laser can operate in continuous wave or pulse mode.
Intended Use:	The DioDent Micro 810/980 Dental Laser System is intended for incision,excision, ablation, vaporization, and/or coagulation of oral soft tissue (including marginal and interdental gingival and epithelial lining of free gingiva). It is also intended for light activation for bleaching materials for teeth whitening, and laser assisted bleaching/whitening for teeth whitening.
Comparison:	The DioDent II, the SIROLaser, and the Twilight are equivalent in operating parameters, physical characteristics, and intended uses. (NOTE: Of the equivalent devices, only the DioDent II is cleared for teeth whitening intended uses).
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hoya ConBio, Inc.
% Ms. Liza Burns
Regulatory Consultant
47733 Fremont Boulevard
Fremont, California 94538

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Re: K063384
Trade/Device Name: DioDent Micro 810 Dental Laser System
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: February 5, 2007
Received: February 9, 2007

Dear Ms. Burns:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Attachment 4:
Indications for Use Statement

Indications for Use Statement

510(k) Number: K063384

Device Name: DioDent Micro 810™, DioDent Micro 980™

Indications for Use: For the incision, excision, ablation, vaporization, and hemostasis of oral soft tissue.

Examples:
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Reduction of bacterial level (decontamination) and inflammation
- Soft tissue crown lengthening
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

Treatment of aphthous ulcers
Vestibuloplasty
Biopsy incision and excision
Lesion (tumor) removal

For light activation for bleaching materials for teeth whitening
For laser-assisted bleaching/whitening for teeth.

Prescription Use ____X____ OR Over-the-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

510(k) Number K063384