



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

March 15, 2016

Millennium Dental Technologies Inc.
Dr. David Harris
Chief Science Officer
10945 South Street Suite 104-A
Cerritos, CA 90703

Re: K151763

Trade/Device Name: PerioLase Nd: YAG Pulsed Dental Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: General and Plastic Surgery
Regulatory Class: Class II
Product Code: GEX
Dated: February 12, 2016
Received: February 16, 2016

Dear Dr. Harris:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k151763

Device Name

PerioLase Nd:YAG Pulsed Dental Laser System

Indications for Use (Describe)

The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary general surgery. The following are the oropharyngeal indications for use for which the device will be marketed:

Oropharyngeal

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies excision and incision
- Crown lengthening
- Hemostatic assistance
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Operculectomy
- Oral papillectomy
- Tissue retraction for impression
- Vestibuloplasty
- Selective ablation of enamel (first degree) caries
- Exposure of unerupted / partially erupted teeth
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment
- 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 level and tooth mobility
- Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."