



Food and Drug Administration
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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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510(k) Summary

Submitter:

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**Date Prepared: June 22, 2015
Date Revised: March 14, 2016**

1. Device Name:

Trade Name: PerioLase Nd:YAG Pulsed Dental Laser System

Common Name: Nd:YAG Pulsed Dental Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Regulation: 21 CFR 878.4810

Classification Panel: General and Plastic Surgery

Device Class: Class II

Product Code: GEX

2. Legally Marketed Predicate Device:

PerioLase, Millennium Dental Technologies, K030290

3. Device Description:

PerioLase Nd:YAG Pulsed Dental Laser System (same as K010771, K014272, and K030290)

The laser head consists of a flashlamp-pulsed Nd:YAG rod in an optical resonant cavity. The energy and the width of each laser pulse are determined by the size and shape of the current pulse through the flashlamp. The current pulse through the flashlamp is controlled by the flashlamp switching circuit. This circuit is based on a solid-state switch that sets the current level and pulse width according to the microprocessor controller. The rate at which the laser pulses are produced, the repetition rate or the pulses/second, is also determined by the microprocessor-controlled switching circuit. The output energy of each laser pulse is measured by

the internal energy monitor. This value is compared to the energy setting by the microcontroller and adjustments are made if necessary.

The laser beam emitted from the laser head is coupled into a fiber-optic cable at the fiber port. The presence of the fiber-optic cable is detected by a sensor such that the laser will not fire if the fiber-optic cable is not in place. The laser aperture is at the distal tip of the fiber. The laser head is cooled by circulating water whose excess heat is removed by an air-water heat exchanger.

The operator controls the laser through the touch screen display. The microcontroller handles all of the logic required to set the energy levels, pulse widths, and repetition rates for the laser output, monitors the output pulses to assure proper output energy, monitors all of the interlocks and sensors, and checks for proper operation of the switches, power supplies, and cooling system. Proper operation of the microcontroller is checked by an independent watchdog microprocessor. The system is designed such that no single fault can result in a system failure.

All of the requirements of the laser safety standards of the CDRH as well as of the IEC 60825-1 standard are incorporated, including the remote interlock connector, the laser stop button, the key control, and the safety and manufacturers labels.

Wavelength	1.064 microns (1064 nm)
Pulse Energy	20 to 300 mJ
Pulse Width	100 µsec to 650 µsec
Repetition Rate	10 to 100 Hz
Average Power	6 Watts maximum
Laser Classification	Class IV

4. Intended Uses:

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 surgery. The following are the oropharyngeal indications for use for which the device will be marketed:

Oropharyngeal

- Abscess incision and drainage
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- Crown lengthening
- Hemostatic assistance
- Fibroma removal

- Frenectomy
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- 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)
- Promotion of 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

5. Summary of a Comparison of Technological Characteristics:

The comparison table provided in the Substantial Equivalence Comparison section of this submission establishes the basis for the determination of substantial equivalence of the PerioLase Nd:YAG Pulsed Dental Laser System to its named predicate device.

The PerioLase Nd:YAG Pulsed Dental Laser System has the identical wavelength, laser medium, beam delivery system type (optical fiber), laser activation method (footswitch), power source (conventional AC power), type of aiming beam and cooling system, and intended uses as its named predicate device.

The PerioLase Nd:YAG Pulsed Dental Laser System's power, pulse duration, energy per pulse, and repetition rate are identical to its named predicate device. There are no differences between the subject and predicate with respect to technology.

6. Nonclinical Performance Data:

The PerioLase Nd:YAG Pulsed Dental Laser System has been evaluated via verification and validation tests and inspections for conformance to applicable regulations and safety standards. Each PerioLase is tested for electrical safety and output characteristics to ensure it meets the design criteria for essential performance, its safety features and functions operate correctly, and it satisfies the performance requirements specified in 21 CFR 1010 and 21 CFR 1040.

Representative data is presented in the Performance section and accompanying appendix of this submission.

7. Clinical Performance Data:

Periodontitis is an infectious disease that progressively destroys the alveolar bone, the periodontal ligament, and the root cementum that attach the teeth to the bone. Destruction of this attachment apparatus results in the loss of teeth. The ultimate aim of periodontal regeneration techniques is to induce or guide healing to regenerate the morphology back to its original configuration. In order to evaluate a regeneration technique experimentally, a notch is made on the root surface at the bottom of a periodontal pocket to provide a histological landmark for the apical extent of the destruction. True periodontal regeneration is then defined by histological evidence of new bone, periodontal ligament, and cementum appearing above the notch on a previously diseased root surface.

Results of a prospective human histological study provide evidence of true periodontal regeneration with new cementum, periodontal ligament, and alveolar bone on previously diseased root surfaces in patients treated nine months earlier with the LANAP® protocol using the PerioLase Nd:YAG Pulsed Dental Laser System.

Eight patients treated with the LANAP® protocol using the PerioLase Nd:YAG laser provided twelve treated teeth that were scheduled for extraction. After nine months of healing, en bloc biopsy extractions were evaluated histologically to assess periodontal wound healing.

Two teeth splintered during histological preparation and were not available for microscopic evaluation. Four teeth healed via long junctional epithelium and one tooth demonstrated new cementum and reattachment apical to the notch.

Five of the remaining ten sites (50%) healed coronal to the notch with true periodontal regeneration, demonstrating new cementum, new periodontal ligament, and new alveolar bone with inserting Sharpey's fibers forming functional reattachments.

Three teeth demonstrating regeneration coronal to the notch also presented with loss of attachment within furcations. These areas demonstrated new bone, new ligament, and new cementum as well.

8. Conclusions:

The PerioLase Nd:YAG Pulsed Dental Laser System is substantially equivalent to the predicate device in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The PerioLase is designed to comply with applicable federal and international safety and performance standards. Histologic data support the new clinical outcome claim. There are no new safety and effectiveness issues.