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Summary of Safety and Effectiveness Information **PerioLase Dental Laser System** ***Premarket Notification, Section 510(k)***	**MILLENNIUM DENTAL TECHNOLOGIES, INC.** **JANUARY 17, 2003**

This 510(K) Summary of safety and effectiveness for the Millennium Dental Technologies PerioLase Dental Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Millennium Dental Technologies, Inc.
Address:	10945 South Street, Suite 104-A Cerritos, CA 90703
Contact Person:	David M. Harris, Ph.D.
Telephone:	(562) 860-2908 – Phone (562) 860-2429 – FAX
Preparation Date:	January 01, 2003
Device Trade Name:	PerioLase Dental Laser
Common Name:	Nd:YAG Pulsed Laser
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device:	PerioLase Dental Laser
Description of the Millennium Dental Technologies PerioLase Dental Laser	The PerioLase is a FR Nd:YAG laser producing laser emission at 1064nm with variable pulse durations (100-650µsec). The laser consists of two interconnected sections: The cabinet which houses the laser head, the power supply, the cooling system and the microprocessor with control panel; and the fiber optic delivery system.
Clinical Performance Data:	The new clinical outcome claim is based on human histological and radiographic data from a controlled prospective University-based clinical study.
Summary Basis of Equivalence:	N/A

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Summary of Safety and Effectiveness Information PerioLase Dental Laser System **Premarket Notification, Section 510(k)**	MILLENNIUM DENTAL TECHNOLOGIES, INC. JANUARY 17, 2003

Intended use:

The following are the oral-pharngeal indications for use for which the device will be marketed:

- Abscess Incision and Drainage
- Apthous 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 re-treatment
- 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 tooth mobility.
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2004

Millenium Dental Technologies, Inc.
c/o David M. Harris, Ph.D.
Bio-Medical Consultants, Inc.
4256 Heyer Avenue
Castro Valley, California 94546

Re: K030290
Trade/Device Name: PerioLase Nd:YAG 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: April 21, 2004
Received: April 27, 2004

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.

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
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 : **K030290**

Device Name(s): *PerioLase Nd:YAG Dental Laser System*

Indications For Use:

The ***PerioLase Nd:YAG Dental Laser System*** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial 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 & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. The following is the additional oral-pharngeal indication for use for which the device will be marketed:

- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.)

Prescription Use ____X____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

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