K010771 1/2 NOV 2 7 2001

Summary of Safety and Effectiveness Information **PerioLase Dental Laser System** ***Premarket Notification, Section 510(k)***	MILLENNIUM DENTAL TECHNOLOGIES, INC. MARCH 13, 2001

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:	10929 South Street, Suite 106-B Cerritos, CA 90703
Contact Person:	David M. Harris, Ph.D.
Telephone:	(562) 860-2908 – Phone (562) 860-1799 – FAX
Preparation Date:	March 13, 2001
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:	Dentica Pulsed Nd:YAG Laser PulseMaster Dental Laser
Description of the Millennium Dental Technologies PerioLase Dental Laser	The PerioLase is an Nd:YAG laser producing laser emission at 1064nm. 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:	N/A
Summary Basis of Equivalence:	The PerioLase is a re-engineered package to provide higher efficiency, a smaller footprint, and less weight. The laser beam, delivered to the tissue via a standard optical fiber, has identical physical characteristics and tissue effects as the predicate device(s). The indications

K010771 3/2

for use and intended uses are also identical. There are no new safety issues.

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
Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
Tissue retraction for Impression
Vestibuloplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

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

Re: K010771
Trade Name: Periolase ND: YAG Dental Laser System
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: October 31, 2001
Received: November 5, 2001

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker, MD

for 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

510(k) Number: K010771

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

Intended Use(s) of the Device:

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 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
- Laser curettage (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Operculectomy
- Sulcular Debridement
- Tissue retraction for Impression
- Vestibuloplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walters

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

510(k) Number K010771

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)