K972325

SEP 19 1997

510(k) Summary
for
PulseMaster® 1000 ST Dental Laser System

1. SPONSOR INFORMATION

American Dental Technologies, Inc.
28411 Northwestern Highway
Southfield, MI 48034

Contact: Mr. John G. Sulewski
Telephone: 248-353-5300

Date Prepared: June 20, 1997

2. DEVICE NAME

Proprietary Name:	PulseMaster® 1000 ST Dental Laser System
Common/Usual Name:	Dental Laser System
Classification Name:	Laser Surgical Instrument
Classification Status:	Class II

3. PREDICATE DEVICES

- PulseMaster® 1000 Dental Laser System
  American Dental Technologies, Inc.
  K922901

- Aurora™ Diode Laser System
  Premier Laser Systems, Inc.
  K954316

4. DEVICE DESCRIPTION AND INTENDED USE

The PulseMaster® 1000 ST Dental Laser System is a portable diode laser system intended for ablating, incising, excising, and coagulating intraoral soft tissue

(including the marginal and interdental gingiva) using a contact fiber optic delivery system. The device is software-controlled and utilizes high brightness diode laser technology to provide similar performance characteristics to Nd:YAG lasers.

5. TECHNOLOGICAL CHARACTERISTICS

The PulseMaster® 1000 ST Dental Laser System is similar in design, function, and intended use to the predicate surgical dental laser systems identified above. The Aurora System is also a diode laser which operates in a continuous or pulsed (gated) mode with similar wavelength range to the PulseMaster® 1000 ST. All three devices are software-controlled, utilize the same type of generic fiber optic delivery system, and have similar performance characteristics with respect to tissue effects.

6. DEVICE TESTING

Testing conducted on the PulseMaster® 1000 ST Dental Laser System includes software verification and validation, and conformance to all relevant requirements of the IEC 601 series of electrical standards.

An in vitro study compared the performance of the PulseMaster® 1000 Nd:YAG System to a diode laser system with output parameters identical to those of the PulseMaster® 1000 ST System. Comparison of width and depth of tissue removed, lateral and deep thermal coagulation, and temperature rise in underlying tissue showed that the performance of the diode laser system was the same or slightly better than that of the Nd:YAG system. No detrimental effects due to temperature or coagulation would be expected for either system during typical clinical usage for oral soft tissue applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. John G. Sulewski
Product Manager
American Dental Technologies
28411 Northwestern Highway
Southfield, Michigan 48034

SEP 19 1997

Re: K972325
Trade Name: PulseMaster® 1000 ST Dental Laser System
Regulatory Class: II
Product Code: GEX
Dated: June 20, 1997
Received: June 23, 1997

Dear Mr. Sulewski:

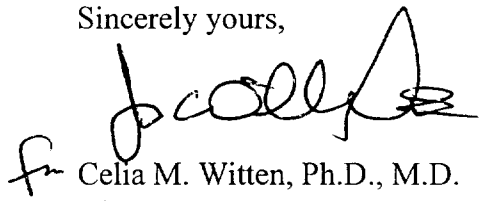
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972321

Device Name: PulseMaster® 1000 ST Dental Laser System

Indications For Use:

The PulseMaster® 1000 ST Dental Laser System is a portable instrument intended for ablating, incising, excising, and coagulating intraoral soft tissue (including the marginal and interdental gingiva) using a contact fiber optic delivery system. The device is indicated for use in the following procedures:

- lesion (tumor) removal
- biopsies
- fibroma removal
- frenectomies and frenotomies
- gingivoplasties
- gingivectomies
- leukoplakia
- operculectomies
- oral papillectomies
- aphthous ulcers
- 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972325

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)