K013908 1/2

FEB 1 2 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

REGULATORY AUTHORITY:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
COMPANY:	**BioLase Technology, Inc.** **981 Calle Amanecer** **San Clemente, California 92673**
CONTACT:	**Ms. Ioana M. Rizoiu** **BioLase Technology, Inc.** **981 Calle Amanecer** **San Clemente, California 92673** **(949) 361-1200 (949) 361-0204 Fax**
TRADE NAME:	***Waterlase Millennium***
COMMON NAME:	**Hydrokinetic tissue cutting system**
CLASSIFICATION NAME:	**Hydrokinetic device**
CLASSIFICATION CODE:	**79 MXF**

EQUIVALENT DEVICES:

Dental handpiece	Dentsply
Dental handpiece	Star Dental
Dental handpiece	Siemens

DEVICE DESCRIPTION:

The ***Waterlase™ Millennium®*** hydrokinetic tissue cutting system is a diverse instrument for performing several dental applications. ***Waterlase™ Millennium®*** utilizes advanced laser and water atomization technologies to incise, excise and ablate intraoral soft and hard tissues safely and effectively. An erbium, chromium, yttrium, scandium, gallium garnet (Er, Cr:YSGG) solid state laser provides optical energy to a user controlled distribution of atomized water droplets. As the water droplets absorb the optical energy hydrokinetic cutting effects result.

The hydrokinetic process refers to the removal of tissues with laser energized water particles. Strong absorption of laser energy by atomized water droplets results in an intense yet controlled water particle micro-expansion and acceleration. The resulting hydrokinetic forces induce mechanical separation of surface material, yielding quick

and clean mechanical tissue removal.

A flexible fiberoptic handpiece delivers the ***Waterlase™ Millennium***'s® unique hydrokinetic tissue cutting technology. A visible light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output and atomized water spray distribution may be adjusted to specific user requirements.

INDICATIONS FOR USE:

Class I, II, III, IV and V cavity preparations

Caries removal

Hard tissue surface roughening or etching

Enameloplasty, excavation of pits and fissures for placement of sealants

Cutting, shaving, contouring and resection of oral osseous tissues (bone)

CAUTIONS AND CONTRAINDICATIONS:

All clinical procedures performed with ***Waterlase™ Millennium®*** must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

SUBSTANTIAL EQUIVALENCE:

The clinical results reported in this Premarket Notification and Feature Comparison Table demonstrate that Waterlase Millennium is substantially equivalent to the Dental handpiece in terms of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Ms. Ioana M. Rizoiu
Vice President, Clinical Research and Development
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673

Re: K013908
Trade Name: Waterlase® Millennium™
Regulation Number: 872.4120
Regulation Name: Bone cutting instrument & accessories
Regulatory Class: II
Product Code: MXF; DZI
Dated: November 21, 2001
Received: November 26, 2001

Dear Ms. Rizoiu:

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,

Miriam C. Provost

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 (if known): K013908

Device Name: Waterlase®Millennium™

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K013908