MAY 27 1999

K990908

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:
Mr. Andrew I. Kimmel
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673
(714) 361-1200 (714) 361-0204 Fax

TRADE NAME: ***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
Microetcher Ab	Danville Engineering, Inc.
KV-1	Kreativ, Inc.

DEVICE DESCRIPTION:

The ***Millennium*™** hydrokinetic tissue cutting system is a diverse instrument for performing several dental applications. ***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 high speed, atomized 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 ***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 - V cavity preparation

Caries removal

Hard tissue surface roughening or etching

Enameloplasty, excavation of pits and fissures for placement of sealants

CAUTIONS AND CONTRAINDICATIONS:

All clinical procedures performed with ***Millennium***™ must be subjected to the same clinical judgement 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:

There are no unique applications, indications, materials or specifications presented herein. This Premarket Notification, reported results from multi-phase *in-vitro* and *in-vivo* clinical trials and Feature Comparison Table demonstrate that Millennium™ is substantially equivalent to the Dental handpiece in terms of safety and efficacy.

FEATURE COMPARISON TABLE

FEATURE	*Millennium*™	Dental handpiece	Microetcher Ab	KV-1	SE
Input Voltage:	115/230 V~ 50/60 Hz	N/A	N/A	N/A	**YES**
Materials:	Medical grade plastics, steel, stainless steel, aluminum, brass and electronic parts and components	Same	Same	Same	**YES**
Indications for Use:	Caries removal, cavity preparation, surface roughening, incision, excision and ablation of soft tissues	Caries removal, cavity preparation	Caries removal, cavity preparation, surface roughening	Caries removal, cavity preparation, surface roughening	**YES**
Cutting Mode:	Mechanical, non-thermal	Same	Same	Same	**YES**
Cutting Medium:	High speed water droplets	Rotating bur	High speed aluminum oxide	High speed aluminum oxide	**YES**
Biocompatible Cutting Medium?	Yes	N/A	No	No	**YES**
Spray Flow Control?	Yes	Yes	N/A	N/A	**YES**
Mode of Operation:	Non-contact	Contact	Non-contact	Non-contact	**YES**
Manufacturer:	BioLase Technology, Inc	Dentsply Laers Research Midwest Star Dental Siemens	Danville Engineering Inc.	Kreativ Inc.	**YES**

CONCLUSION:

Millennium™ is substantially equivalent to several available, established dental technologies. Safety and efficacy have been demonstrated through *in-vitro*, *in-vivo* and clinical trials on animals and humans. Technically, Millennium™ performs through the same mechanical mechanism as other technologies but has the benefit of using a biocompatible agent as its cutting medium. Evidence of equivalence has been demonstrated through:

- Clinical evaluation in randomized, double-blinded trials
- Pulp temperature studies
- Scanning Electron and Optical Microscopy
- Equivalent performance specifications
- Promotional materials for equivalent systems
- Equivalent intended uses
- Feature comparison table

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 1999

Mr. Andrew I. Kimmel
Vice President for Regulatory Affairs
Biolase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673

Re: K990908
Trade Name: Millennium
Regulatory Class: II
Product Code: MXF
Dated: March 15, 1999
Received: March 18, 1999

Dear Mr. Kimmel:

This letter corrects our substantially equivalent letter of May 27, 1999 regarding the Indication for Use by adding the phrase, "For use on adult and pediatric patients."

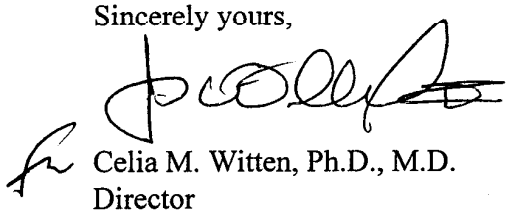
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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): 990908

Device Name: Millennium™

Indications for Use:

For use on adult and pediatric patients for the following:

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

Caries removal

Hard tissue surface roughening or etching

Enameloplasty, excavation of pits and fissures for placement of sealants

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990908