

2/24/99

K 990219

**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 dental system

**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*<sup>TM</sup>'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

#### **CAUTIONS AND CONTRAINDICATIONS:**

All clinical procedures performed with *Millennium*<sup>TM</sup> 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*<sup>TM</sup> is substantially equivalent to the Dental handpiece in terms of safety and efficacy.

### FEATURE COMPARISON TABLE

FEATURE	<i>Millennium</i> <sup>TM</sup>	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:

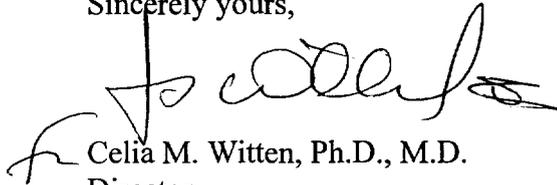
Millennium<sup>TM</sup> is substantially equivalent to several available, established dental technologies. Safety and efficacy have been demonstrated through *in-vitro*, *in-vivo* and clinical trials on animals and humans. Technically, Millennium<sup>TM</sup> performs through the same mechanical mechanism 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

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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): K990219

Device Name: Millennium™

Indications for Use:

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

Caries removal

Hard tissue surface roughening or etching

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

K990219

Prescription Use   
(Per 21 CFR 801.109)

or Over-The-Counter-Use \_\_\_\_\_