NOV 1 3 2008

510(k) SPECIAL Summary

(As required by 21CFR807.92, 21CFR807.81(a)(3), FDA Memorandum #K97-1)

K083069

Date Prepared:	**October 13, 2008**
Company:	**Biolase Technology, Inc.** **4 Cromwell** **Irvine, CA 92618** **Tel: (949) 361-1200** **Fax: (949) 273-6680**
Contact:	**Ms. Ioana M. Rizoiu** **VP, Clinical R&D** **Tel: (949) 226-8144** **email: irizoiu@biolase.com**
Trade Name:	***ezlase™ 10W***
Common Name:	**Dental Diode Laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX, a Class II device**
Predicate Devices:	***ezlase™*** **Biolase Technology, Inc** **K061898 (January 26, 2007)** **Twilight™** **Biolase Technology, Inc** **K991994 (September 10, 1999)**

DEVICE DESCRIPTION:

The ***ezlase™ 10W*** dental diode laser system may be used to perform various dental soft tissue applications. The system uses advanced laser technology to incise, excise, vaporize, coagulate and ablate intraoral soft tissues. An Indium Gallium Arsenide Phosphorus solid-state laser diode emits infrared laser energy to the various oral soft tissues targeted during a procedure. This energy is transmitted via a flexible fiberoptic cable to the handpiece that emits the energy to the targeted tissue site. A visible light is emitted at the same time to visually pinpoint the treatment location. The power output and pulse width may be adjusted to specific user requirements.

INDICATIONS FOR USE:

Dental Soft Tissue Indications for:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

Laser Periodontal procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

CONTRAINDICATIONS:

All clinical procedures performed with the ***ezlase™ 10W*** 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, which might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea, and immune system deficiency, or any medical conditions or medications that may contraindicate use of certain

light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

CONCLUSION:

There are no new indications requested for this device in this Special 510(k). Substantial equivalency for the ***ezlase™ 10W*** has been determined through comparison to previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biolase Technology, Inc.
% Ms. Ioana Rizoiu
VP, Clinical Research & Development
4 Cromwell
Irvine, California 92618

NOV 13 2008

Re: K083069
Trade/Device Name: *ezlase™ 10W*
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 13, 2008
Received: October 15, 2008

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 083069

Device (Trade) Name: *ezlase™ 10W*

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(Division Sign-Off)
Division of General, Restorative,
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Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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