510(k) Summary
(As required by 21CFR807.92)

DEC 22 2008

Date Prepared:	**October 1, 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™***
Common Name:	**Dental Diode Laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX, a Class II device**
Predicate Devices:	**Twilight™** **Biolase Technology, Inc** **Ceralas D Diode Laser Systems** **Ceramoptic, Inc. (Biolitec, Inc.)** **Vectra™** **Xintec Corp., DBA Convergent Laser Technologies**

DEVICE DESCRIPTION:

The ***ezlase™*** dental diode laser system is currently used to perform various [redacted] The system uses advanced laser technology to [redacted] An Indium Gallium Arsenide Phosphorus solid-state laser diode emits infrared laser energy to the various oral soft tissues targeted during 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:

This device may be used for the following indications:

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

CONTRAINDICATIONS:

All clinical procedures performed with the ***ezlase***™ 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.

SUBSTANTIAL EQUIVALENCE:

The purpose of this 510(k) is to expand the current ***ezlase***™ indications for use (K061898) to include teeth whitening, an indication already cleared by the FDA for equivalent medical devices as part of the following 510(k) submissions: **K003385** (*Twilite*™), **K993002, K050824, K072106,** (*Ceralas D laser systems*), and **K060114** (*Vectra*™). Based on this comparison, the ***ezlase***™ is substantially equivalent in relation to previous cleared devices.

CONCLUSION:

The indications requested by this 510(k) are the same as those previously cleared by the FDA for other equivalent devices. Substantial equivalency for the ***ezlase***™ 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 M. Rizoiu
VP, Clinical R & D
4 Cromwell
Irvine, California 92618

DEC 22 2008

Re: K082938
Trade/Device Name: ezlase™
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: December 16, 2008
Received: December 17, 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082938

Indications for Use Statement

510(k) Number: K_____

Device (Trade) Name: *ezlase*™

Indications for Use:

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

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)

David Krause for MKM 12/22/2005

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

510(k) Number K082938