510(k) Summary

(As required by 21CFR807.92)

APR 14 2009

Date Prepared:	**December 4, 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:	**Diode Laser**
Classification Name:	**Infrared Lamp (21CFR §890.5500**
Product Code:	**ILY**
Predicate Devices:	**Powerlaser** **PowerMedic ApS,** **Thor VR Single Diode Laser Treatment** **Thor International Ltd.** **MedX LPT 200 Tethered Laser &** **MedX LPS 200 Portable Laser** **MedXElectronics, Inc.**

DEVICE DESCRIPTION:

The ***ezlase™*** diode laser system, was cleared for dental soft tissue indications under K061898 and K083069. The system uses a Gallium Aluminum Arsenide (GaAlA) and/or an Indium Gallium Arsenide Phosphorus (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiberoptic cable to a handpiece that emits the energy to the targeted site. A visible light is emitted at the same time to visually identify the treatment location.

INDICATIONS FOR USE:

The ezlase diode system emits energy in the near- infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

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, malignancies, 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 (**K**061898, **K**083069) to include therapeutic indications. The requested indications have already been cleared by the FDA for several equivalent medical devices, including the following: **K070516** (*Powerlaser*), **K070024** (*Thor VR Single Diode Laser Treatment*), **K080318** (*Alma Laser NIR Module)* and **K082707** (*MedX LPT200 and LPS200*). Based on this comparison, the ***ezlase***™ is substantially equivalent in relation to previously 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

APR 14 2009

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

Re: K083595
Trade/Device Name: *ezlase*™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 20, 2009
Received: March 24, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
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 083595

Device (Trade) Name: *ezlase*™

Indications for Use:

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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

510(k) Number K083595