# 510(k) Summary of Safety and Effectiveness

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

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| ***Date Prepared:*** | **March 3, 2010** |
| ***Company:*** | **Biolase Technology, Inc.**<br>**4 Cromwell**<br>**Irvine, CA 92618**<br>**Tel: (949) 361-1200** |
| ***Contact:*** | **Ms. Ioana M. Rizoiu**<br>**VP, Clinical R&D**<br>**Tel: (949) 226-8144**<br>**Fax: (949) 273-6680**<br>**email: irizoiu@biolase.com** |
| ***Trade Name:*** | ***iLase***™ |
| ***Common Name:*** | **Dental Diode Laser** |
| ***Classification Name:*** | **Surgical laser instrument** |
| ***Classification Code:*** | **79 GEX, a Class II device** |
| ***Predicate Devices:*** | ***ezlase***®<br>**Biolase Technology, Inc**<br>**K061898 (1/26/07), K083069 (11/13/08)**<br><br>**Styla Microlaser**<br>**Zap Lasers, LLC**<br>**K081214 (5/14/2008)** |

**DEVICE DESCRIPTION:**

The ***iLase***™ dental soft tissue laser is a surgical device designed for a wide variety of dental soft tissue procedures. It is capable of storing up to twelve soft tissue procedure settings.

The ***iLase***™ uses a solid state laser diode as a source of invisible infrared radiation. The energy is delivered to the treatment site via the ezTip®, a single-use fiber optic tip assembly. Several types of ezTips® are available for use with the ***iLase***™ to perform different procedures. The ***iLase***™ is a Class II medical laser device and is sold only to licensed practitioners.

The ***iLase***™ system consists of two elements:

I. The handpiece contains the laser diode, the replaceable fiber optic ezTip®, removable shroud, a microprocessor, control program, memory, integrated finger switch, organic LED (OLED) display, and rechargeable battery. The handpiece delivers laser energy, under user control, to the treatment site.

II. The battery charger is used for charging and storing the handpiece. Discharged batteries are placed in receptacles in the charging station where they are automatically recharged. The charging station is furnished with a low voltage power supply.

**INDICATIONS FOR USE:**

**Dental Soft Tissue Indications:**
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
- Tissue retraction for impression

**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 ***iLase***™ 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 that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, 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 patient's physician is advisable when doubt exists regarding treatment.

**CONCLUSION:**

***iLase***™ is substantially equivalent to devices previously cleared for marketing. ***iLase***™ performs the same indications for use through the same mechanism as other devices cleared by the FDA. Substantial equivalency for the ***iLase***™ has been determined through comparison to previously cleared dental diode lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 12 2010

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

Re: K093852
Trade/Device Name: iLase™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 04, 2010
Received: March 09, 2010

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

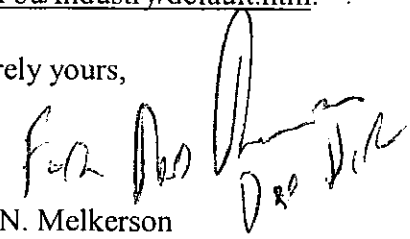
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number:** K 093852

**Device (Trade) Name:** *iLase*™

**Indications for Use:**

***Dental Soft Tissue Indications for:***

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- Vestibuloplasty
- Tissue retraction for impression

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- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket

K093852



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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)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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