510(k) Summary of Safety and Effectiveness Information

DEC - 7 2009

Regulatory Authority:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
Company:	**Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618**
Contact:	**Ms. Ioana M. Rizoiu Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618 Tel: (949) 226-8144 Fax: (949) 273-6680**
Trade Name:	***Waterlase®MD***
Common Name:	**Er,Cr:YSGG laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX, MXF, DZI a Class II device**
Equivalent Devices:	**KaVo Key Laser III 1243 US**

DEVICE DESCRIPTION:

The ***Waterlase®MD*** dental laser system is a device used to perform a variety of dental soft and hard tissue indications. For hard tissue procedures the ***Waterlase®MD*** uses the Erbium,Chromium:Yttrium,Scandium,Gallium Garnet (Er,Cr:YSGG) laser in combination with advanced water atomization spray technology to cut, remove, shave, contour, roughen and etch tissues. Soft tissue procedures are performed using two different modes of operation, H and S, where direct Er,Cr:YSGG laser energy is applied to incise, excise or ablate these tissues. For soft tissue procedures the water spray is applied for hydration, cooling or to keep tissues and the field of view clean. For hard tissue applications the spray is part of the tissue removing process as well as hydration, cooling and keeping tissues and field of view clean.

A flexible fiber optic terminated into the handpiece delivers the ***Waterlase®MD*** laser energy to the end fiber tip and target. A visible aiming light emitted from the handpiece's distal end pinpoints the area of treatment. Three fiber optic ports provide illumination from the handpiece to the tissue site in addition to the center beam emitting source. In both hard and soft tissue applications the power output, pulse duration, repetition rate (frequency) and air and water flow rates are adjustable to specific user requirements. The spot size and spot geometry can also be varied by changing tips which include different diameters and end configurations.

INDICATIONS FOR USE:

Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

All clinical procedures performed with ***Waterlase® MD*** must be subject 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, but are not limited to, 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:

The indications included herein are the same as indications that have been previously cleared by the FDA for an equivalent device. Substantial equivalency for the ***Waterlase®MD*** has been determined through comparison to a previously cleared device.

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

DEC - 7 2009

Ms. Ioana M. Rizoiu
Vice President, Clinical Research & Development
Biolase Technology, Incorporated
4 Cromwell
Irvine, California 92618-1816

Re: K091746
Trade/Device Name: Waterlase® MD
Regulation Number: 21CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 18, 2009
Received: November 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.

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,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091746

Indications for Use

510(k) Number_____:

Device Name: Waterlase® MD

Indications for Use:

Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.

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)

Kei Mulay for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 091746