K090181



FEB 1 1 2009

# *Special* 510(k) Summary of Safety and Effectiveness Information

**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**
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**Trade Name:** ***Waterlase® MD***

**Common Name:** **Er,Cr:YSGG laser**

**Classification Name:** **Surgical laser instrument**

**Classification Code:** **79 GEX, a Class II device**

**Equivalent Devices:** ***Waterlase® MD***
Biolase Technology, Inc.
K031140, July 7, 2004

**Device Description:**

The ***Waterlase®MD*** is a dental laser device previously cleared by the FDA for hard and soft tissue dental indications (K031140, K071363). The only changes from the previously cleared device are the addition of the Turbo handpiece, which combines minor software and graphics changes that will be added to the ***Waterlase®MD*** laser system. This software does not change the operational software, but adds a "Select" icon on the control panel, and unassigned pre-sets fields for use by the dentist to store preferred setting selections. There are no other hardware or software changes to the ***Waterlase®MD*** device pending herein when compared to the device cleared under K031140 and K071363.

Materials used for the Turbo handpiece are the same as those for the MD Gold handpiece. Biocompatibility testing of these materials was conducted in compliance with 21 CFR Part 820, Quality System Regulation, Subpart C, Sec. 820.30 – Design Controls, and ISO 13485-2003, Section 7.3 – Design and Development; documented results (on file) confirmed there is no biocompatibility risk presented by these materials.

## Indications for Use:

***General Indications****

- Class I, II, III, IV and V cavity preparation
- Caries removal
- Hard tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

* For use on adult and pediatric patients

*Root Canal Hard Tissue Indications*

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

*Root Canal Disinfection*

- Laser root canal disinfection after endodontic treatment

*Endodontic Surgery (Root Amputation) Indications*

- Flap preparation = incision of soft tissue to prepare a flap and expose the bone.
- Cutting bone to prepare a window access to the apex (apices) of the root(s).
- Apicoectomy – amputation of the root end.
- Root end preparation for retrofill amalgam or composite.
- Removal of pathological tissues (*i.e.*, cysts, neoplasm or abscess) and hyperplastic tissues (*i.e.*, granulation tissue) from around the apex

***NOTE:*** *Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*

*Bone Surgical Indications*

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)
- Osteotomy

***Soft Tissue Indications including Pulpal Tissues****

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal

- Flap preparation = incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation = incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty

- Gingival incision and excision
- Hemostasis
- implant recovery
- Incision and drainage of abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Root canal debridement and cleaning
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

***NOTE:*** *Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*

- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

* For use on adult and pediatric patient

***Laser Periodontal Procedures***

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining

  junctional epithelium
- Removal of granulation tissue from bony defects

- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleedingindex, probe depth, attachment loss and tooth mobility)
- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening

*All Contraindications remain the same as for the previously cleared device, Waterlase®MD (K031140)*

**Contraindications:**

All clinical procedures performed with the ***Waterlase®MD*** 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, 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 the patient's physician is advisable when doubt exists regarding treatment.

**Conclusion:**

The indications included herein are the same as the indications that have been previously cleared by the FDA for the ***Waterlase®MD (K031140, K071363).*** Substantial equivalency for the ***Waterlase®MD*** with the Turbo Handpiece has been determined through comparison to the previously cleared ***Waterlase®MD***.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2009

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

Re: K090181
Trade/Device Name: Waterlase®MD (Turbo Handpiece)
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: January 23, 2009
Received: January 26, 2009

Dear Mr. Christensen:

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

# Indications for Use

510(k) Number (if known): _____

Device Name: Waterlase®MD (Turbo Handpiece)

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- Root end preparation for retrofill amalgam or composite.
- Removal of pathological tissues (*i.e.*, cysts, neoplasm or abscess) and hyperplastic tissues (*i.e.*, granulation tissue) from around the apex

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- Excisional and incisional biopsies
- Exposure of unerupted teeth

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

510(k) Number K090181

- Fibroma removal
- Flap preparation = incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation = incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
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- Gingival incision and excision
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- implant recovery
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Division of General, Restorative, and Neurological Devices

510(k) Number K090181

- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening

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)**

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**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K090181