ATTACHMENT 7
510(k) Summary of Safety and Effectiveness Information

AUG 11 2010

Date Prepared: July 13, 2010

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company:
Biolase Technology, Inc.
4 Cromwell
Irvine, CA 92618

Contact:
Ms. Ioana Rizoiu
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Irvine, CA 92618
Tel: (949) 226-8144
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Trade Name: ***Waterlase® MD Turbo Plus***

Common Name: Er,Cr:YSGG laser

Classification Name:
-Powered laser surgical instrument
-System, dental, hydrokinetic, caries removal & cavity preparation
-Drill, bone, powered

Classification Code(s): 79 GEX, MXF, DZI, a Class II device

Equivalent Devices:
Waterlase® MD
Biolase Technology, Inc.
K031140, July 7, 2004; *K071363*, February 12, 2008

Waterlase® MD Turbo
Biolase Technology, Inc.
K090181, February 11, 2009; *K083927*, October 1, 2009;
K091746, December 7, 2009

Device Description:

The ***Waterlase®MD Turbo Plus*** is a dental laser device indicated for incision, excision, removal, and specific dental therapies, such as root canal therapy and periodontal therapy. All indications for use submitted for the ***Waterlase®MD Turbo Plus*** have been previously cleared by the FDA and there are no new indications included for this device.

K 101658

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

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- 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 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)

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- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening
- Removal of subgingival calculi in periodontal pockets with peridonditis by closed or open curettage
- Waterlase MD Er,Cr:YSGG assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

Contraindications:

All clinical procedures performed with the ***Waterlase®MD Turbo Plus*** 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, or an immune system deficiency. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

Discussion:

The ***Waterlase®MD Turbo Plus*** has been compared and determined to be equivalent to all predicated devices presented as part of the Substantial Equivalency discussion. In summary, for changes to the higher energy per pulse of 600 mJ, ***Waterlase®MD Turbo Plus*** is equivalent to Waterlase® MD Turbo (predicate). The two devices have the same energy per square cm when compared at settings related to the preparation of class II cavities. Equivalency of the ***Waterlase®MD Turbo Plus*** was also established through performance data in a comparison of class II cavity preparations prepared at 600 mJ per pulse with the ***Waterlase®MD Turbo Plus*** to the same prepared with the Waterlase® MD Turbo (predicate, K090181). In addition, the ***Waterlase®MD Turbo Plus*** operated at 600 mJ per pulse is also equivalent to the other predicated devices cleared by the FDA under K030146 and K070355. For the additional pulse frequencies of 75 and 100Hz, the ***Waterlase®MD Turbo Plus*** device was determined safe and effective through performance data. Gingivoplasties performed at the two new frequencies on pig jaw gingiva demonstrated that the ***Waterlase®MD Turbo Plus*** is a safe and effective device for the gingivoplasty indication. Gingivoplasty is an indication already cleared for the listed predicate devices.

Conclusion:

The indications included herein are the same as the indications that have been previously cleared by the FDA for the Waterlase®MD predicates under K031140, K071363, K090181, K083927, and K091746, as well as other dental laser predicates, such as K001527, K070355, K983100, K000805, K030146, and K073074. No clinical performance data is required for this submission. Therefore, substantial equivalency for the ***Waterlase®MD Turbo Plus*** has been determined through comparison to these previously cleared dental laser devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biolase Technology, Inc.
% Ms. Ioana Rizoiu
Vice President of Clinical Research
and Development
4 Cromwell
Irvine, California 92618

AUG 11 2010

Re: K101658
Trade/Device Name: Waterlase® MD Turbo Plus
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, MXF
Dated: June 07, 2010
Received: June 11, 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,

for Peter D. Rumm no mp/f

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

510(k) Number (if known): K101658

Device Name: Waterlase®MD Turbo Plus

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- Exposure of unerupted teeth
- Fibroma removal

Neil R. Ogden for mam

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

510(k) Number K101658

- Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
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- Gingival troughing for crown impressions
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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101658

- 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)
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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)

Mark R. Dyken for mxn
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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101658