K091922

# 510(k) *SPECIAL* Summary

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

JUL 14 2009

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| ***Date Prepared:*** | **June 25, 2009** |
| ***Company:*** | **Biolase Technology, Inc.**<br>**4 Cromwell**<br>**Irvine, CA 92618**<br>**Tel: (949) 361-1200**<br>**Fax: (949) 273-6680** |
| ***Contact:*** | **Ms. Ioana M. Rizoiu**<br>**VP, Clinical R&D**<br>**Tel: (949) 226-8144**<br>**email: irizoiu@biolase.com** |
| ***Trade Name:*** | ***Waterlase® C100*** |
| ***Common Name:*** | **Er,Cr:YSGG laser** |
| ***Classification Name:*** | **Surgical laser instrument** |
| ***Classification Code:*** | **79 GEX, MXF, DZI a Class II device** |
| ***Predicate Devices:*** | ***Waterlase®***<br>**Biolase Technology, Inc**<br>**K030523 (January 30, 2004), K071363 (February 12, 2008)**<br><br>***Waterlase® 3.0***<br>**Biolase Technology, Inc**<br>**K081589 (June 12, 2008)** |

**DEVICE DESCRIPTION:**

The ***Waterlase® C100*** dental laser system is a diverse device utilized to perform a variety of dental applications. For hard tissue procedures the ***Waterlase® C100*** uses the Erbium, Chromium, Yttrium, Scandium, Gallium Garnet (Er,Cr:YSGG) laser in combination with advanced water atomization spray technology to cut, remove, roughen and etch tissues. Soft tissue procedures are performed using a different mode of operation where direct Er,Cr:YSGG laser energy is applied to incise, excise or ablate these tissues. In soft tissue procedures the water spray is applied for hydration, cooling or to keep tissues clean. For hard tissue applications the spray is part of the tissue removing process as well as hydration, cooling and keeping tissues clean.

A flexible fiberoptic handpiece delivers the ***Waterlase® C100*** laser energy. A visible light emitted from the handpiece distal end pinpoints the area of treatment. In both hard and soft tissue applications the power output, pulse energy, repetition rate (frequency) and air and water flow rates are adjustable to specific user requirements.

**INDICATIONS FOR USE:**

This device may be used for the following indications (previously cleared under submissions K030523, K071363, and K081589):

***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 instrumentation

***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 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

**CONTRAINDICATIONS:**

All clinical procedures performed with the ***Waterlase® C100*** 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 the patient's physician is advisable when doubt exists regarding treatment.

**CONCLUSION:**

The indications included herein are the same as indications that have been previously cleared by the FDA for the predicate device. Substantial equivalency for the ***Waterlase®C100*** 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

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

JUL 14 2009

Re: K091922
Trade/Device Name: Waterclase® C100
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: June 25, 2009
Received: June 30, 2009

Dear Mr. 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): _____

Device Name: Waterlase® C100

Indications for Use:

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and Restorative Devices

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- Operculectomy
- Operculectomy

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and Restorative Devices

510(k) Number K091922

- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
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- Reduction of gingival hypertrophy
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* For use on adult and pediatric patient

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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