

OCT 10 2003

K030539

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

**Regulatory
Authority:**

Safe Medical Devices Act of 1990,
21 CFR 807.92

Company:

BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673

Contact:

Ms. Ioana M. Rizoiu
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673
(949) 361-1200 (949) 361-0204 Fax

Trade Name:

LaserSmile™

Common Name:

Dental diode laser

Classification Name:

Surgical laser instrument

Classification Code:

79 GEX

Equivalent Devices:

BioLase Technology, Inc.

Waterlase®

BioLase Technology, Inc.

Twilite™

Device Description:

The *LaserSmile™* dental diode laser system may be used to perform several dental applications. *LaserSmile™* uses advanced laser technology to incise, excise and ablate intraoral soft tissues and to activate a bleaching material for whitening/bleaching teeth safely and effectively. A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues and tooth bleaching compounds.

A flexible fiberoptic handpiece delivers the *LaserSmile™* laser energy. A visible light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output and pulse may be adjusted to specific user requirements.

Indications for Use:

Dental Soft Tissue Indications for:

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

- 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

Laser Periodontal procedures, including:

- 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 and junctional epithelium
- 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.)

Tooth Whitening Indications:

- Laser assisted whitening/bleaching of teeth.
- Light activation for bleaching materials for teeth whitening.

Contraindications:

All clinical procedures performed with *LaserSmile™* 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, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Patients with periodontal disease and/or exposed root surfaces are not candidates for laser tooth bleaching/whitening. Also, patients with damaged or fissured enamel are not candidates for laser bleaching/whitening.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. All the submitted indications for use retain the same meaning as their equivalent indications cleared by the FDA in K991994 (*Twilite™*, original indications for use), and in K011041 (*Waterlase®*, expanded indications for use).

Conclusion:

LaserSmile™ is substantially equivalent to dental products previously cleared for marketing. *LaserSmile™* performs the same indications for use through the same mechanism as the other cleared devices. Evidence of equivalence has been demonstrated through the following:

- Equivalent performance specification
- Equivalent intended use
- Feature comparison table



OCT 10 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ioana M. Rizoiu
Vice President, Clinical Research and Development
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673

Re: K030539
Trade/Device Name: LaserSmile™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 11, 2003
Received: July 16, 2003

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 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.

Page 2 – Mr. Daryl Wisdahl

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030539

Device Name: **LaserSmile™**

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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

Laser Periodontal procedures, including:

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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030539

Tooth whitening procedures, including:

Light activation for bleaching materials for teeth whitening.
Laser-assisted whitening/bleaching of teeth.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or Over-The-Counter-Use _____

miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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