

SEP 10 1999

K991994

**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, California 92673

Contact: Ms. Ioana M. Rizoiu
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673
(714) 361-1200 (714) 361-0204 Fax

Trade Name: *Twilight*TM

Common Name: Dental diode laser

Classification Name: Surgical laser instrument

Classification Code: 79 GEX

Equivalent Devices:

American Dental Technologies	<i>PulseMaster</i> TM
Dentek-LaserSystems	<i>LD-15</i> TM
Premier Laser Systems	<i>Aurora</i> TM

Device Description:

The *Twilight*TM dental diode laser system may be used to perform several dental applications. *Twilight*TM uses advanced laser technology to incise, excise and ablate intraoral soft tissues safely and effectively. A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues.

A flexible fiberoptic handpiece delivers the *Twilight*TM 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:

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

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

Gingival troughing for crown impressions
Gingivectomy
Gingivoplasty
Gingival incision and excision
Hemostasis
Implant recovery
Incision and drainage of abscess
Laser Assisted Uvulopaletoplasty (LAUP)
 This laser is effective for cutting, ablating, coagulating and removing oropharangeal soft tissue that has been diagnosed as anatomically abnormal or naturally occurring hypertrophic which has been identified and confirmed as being associated with chronic palatal snoring.
Leukoplakia
Operculectomy
Oral papillectomies
Pulpotomy
Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy
Reduction of bacterial level (decontamination) and inflammation
Soft tissue crown lengthening
Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
Treatment of aphthous ulcers
Vestibuloplasty

Cautions and Contraindications:

All clinical procedures performed with *Twilight*[™] must be subjected to the same clinical judgement 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.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. *Twilight*[™] is identical to several other diode laser systems cleared by the FDA. Equivalent devices include: Premier, *Aurora*[™](K954316), American Dental Technologies, *PulseMaster*[™] (K972325) and Dentek, *LD-15*[™] (K974057) for general dental soft tissue applications, Premier, *Aurora*[™] (K981379) for pulpotomy and American Dental Technologies, *PulseMaster*[™] (K961269) and Premier, *Aurora*[™] (K974586) for sulcular debridement.

Conclusion:

Twilight[™] is substantially equivalent to several available, established dental diode laser products. *Twilight*[™] performs through the same mechanism as other diode laser technologies.

- Evidence of equivalence has been demonstrated through:

- Equivalent performance specifications
- Promotional materials for equivalent systems
- Equivalent intended uses



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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, California 92673

Re: K991994
Trade Name: Twilight™
Regulatory Class: II
Product Code: GEX
Dated: June 11, 1999
Received: June 14, 1999

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

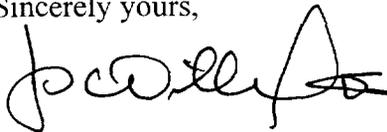
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

DUPLICATE

K 991994/A2

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Device Name: *Twilight™*

Indications for Use:

Ear, Nose and Throat and Oral Surgery:

Hemostasis, incision, excision, ablation and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity.

Examples:

- Removal of benign lesions from ear, nose and throat.
- Excision and vaporization of vocal cord nodules and polyps.
- Incision and excision of carcinoma in-situ.
- Ablation and vaporization of hyperkeratosis.
- Excision of carcinoma of the larynx.
- Laryngeal papillomectomy.
- Excision and vaporization of herpes simplex I and II.

Arthroscopy:

Hemostasis, incision, excision, vaporization and ablation of joint tissues during arthroscopic surgery.

Examples:

- Meniscectomy
- Synovectomy
- Chondromalacia

Gastroenterology:

Hemostasis, incision, excision and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy.

Examples:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

General Surgery, Dermatology & Plastic Surgery, and Podiatry:

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

Examples:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy

[Signature]
 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K991994

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 FDA/CDRH/ODE/DMC

General Surgery, Dermatology & Plastic Surgery, and Podiatry (continues):

Examples:

Debridement of decubitus ulcer
Hepatobiliary
Mastectomy
Dermabrasion
Vaporization & hemostasis of capillary hemangioma
Excision, vaporization & hemostasis of abdominal tumors
Excision, vaporization & hemostasis of rectal pathology
Pilonidal cystectomy
Hemiorrhaphy
Adhesiolysis
Parathyroidectomy
Laparoscopic cholecystectomy
Thyroidectomy
Resection of organs

GI/GU:

Excision, vaporization, and hemostasis of abdominal and rectal tissues.

Examples:

Hemorrhoidectomy
Excision, vaporization, and hemostasis of rectal pathology
Excision, vaporization, and hemostasis of abdominal tumors

Gynecology:

Ablation, excision, hemostasis and vaporization of tissue.

Examples:

Endometrial ablation
Excision or vaporization of condylomata acuminata
Vaporization of CIN (cervical intraepithelial neoplasia)
Cervical conization
Menorrhagia

Neurosurgery:

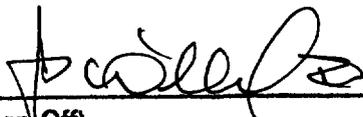
Hemostasis of tissue.

Example:

Hemostasis in conjunction with meningiomas

Ophthalmology:

Retinal photocoagulation
Diabetic retinopathy



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Division of General Restorative Devices *K991994*
510(k) Number _____

Pulmonary Surgery:

Hemostasis, vaporization, and excision of tissue.

Examples:

Tracheobronchial malignancy or stricture

Pulmonary Surgery (continues):

Hemostasis, vaporization, and excision of tissue.

Examples:

Benign and malignant pulmonary obstruction

Urology:

Hemostasis, vaporization and excision of tissues.

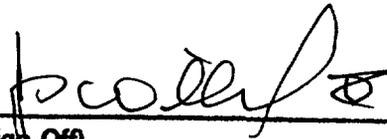
Examples:

Vaporization of urethral tumors
Release of urethral stricture
Removal of bladder neck obstruction
Excision and vaporization of condyloma
Lesions of external genitalia.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

or Over-The-Counter-Use



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Division of General Restorative Devices

510(k) Number

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