

10971459

**510(K) SUMMARY OF SAFETY  
AND EFFECTIVENESS INFORMATION**

**REGULATORY AUTHORITY:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

JUL 18 1997

**COMPANY NAME/CONTACT:**

**Company:** BioLase Technology, Inc.  
981 Calle Amanecer  
San Clemente, California 92673

**Contact:** Mr. Andrew Kimmel  
BioLase Technology, Inc.  
981 Calle Amanecer  
San Clemente, California 92673  
(714) 361-1200 (714) 361-0204 Fax

**Trade Name:** *DermaLase™*

**Common Name:** Surgical Laser

**Classification Name:** Surgical Laser System

**Classification Code:** 79GEX

**EQUIVALENT DEVICES:**

CB Erbium/2.94	Continuum Biomedical, Inc.	K961748
Trilase 2940™ Erbium laser system	Schwartz Electro-Optics	K954013
MCL 29 Dermablade™	Aesculap-Meditec	K964128
Elmer™	Biolase Technology, Inc.	K952118

**DESCRIPTION OF THE DEVICE:**

The *DermaLase™* laser system consists of two main components: the laser module and the delivery system.

The Laser Module contains the laser resonator cavity, power supplies, closed loop internal cooling system and TTCS™ tissue irrigation and cooling module. Microelectronics circuits and system Control Panel are housed inside the laser console as well.

The Control Panel provides access to all system controls. Actions are initiated through a touch sensitive membrane keypad. The display screen is back lighted for easy viewing.

BioLase currently offers two options for laser energy delivery: a fiber optic based delivery system and an articulated arm based delivery system. The fiber optic system utilizes either a contact or non-contact hand piece. The articulated arm based delivery system utilizes either a contact or non-contact point delivery hand piece.

#### **Indications for Use:**

Use of the *DermaLase™* laser system is restricted to the incision, excision, ablation, vaporization and hemostasis of soft tissue

#### **SUBSTANTIAL EQUIVALENCE:**

This Premarket Notification demonstrates that the laser systems described herein are substantially the same as the *DermaLase™* laser system.

Several different surgical, dental and dermatological laser systems and features are equivalent to those of the *DermaLase™* laser unit. The internal components of the *DermaLase™* are almost identical to an earlier, currently 510(k) cleared Biolase erbium laser product, *Elmer™* (K952118). The *Elmer™* laser system produces laser light at the exact same wavelength, power and frequency as the *DermaLase™* and includes Biolase's *Target Tissue Cooling System™* for tissue cooling and irrigation.

Other laser manufacturers such as Schwartz Electro-Optics, Continuum Biomedical and Aesculap-Meditec are currently marketing products with similar performance specifications as the *DermaLase™* and for similar indications for use.

#### **CONCLUSION:**

The *DermaLase™* is Substantially Equivalent to several available surgical laser systems. As noted above, the laser wavelength and air and water tissue cooling and irrigation spray are equivalent to an earlier Biolase product, *Elmer™* (K952118). Several other equivalent erbium laser devices have similar performance specifications, promotional materials and indications for use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 18 1997

Mr. Andrew Kimmel  
BIOLASE Technology, Inc.  
981 Calle Amanecer  
San Clemente, California 92673

Re: K971459  
Trade Name: DermaLase Er, Cr:YSGG Laser with Contact and Non-contact  
Handpieces  
Regulatory Class: II  
Product Code: GEX  
Dated: April 18, 1997  
Received: April 21, 1997

Dear Mr. Kimmel:

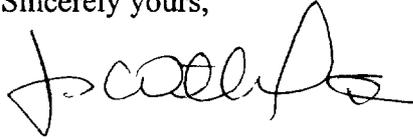
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 requirements, 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.

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,



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

510 (k) Number (if known): K971459

Device Name: DermaLase

Indications For Use:

Use of the device is indicated for the incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, cheilitis, keloids, verrucae, skin tags, keratosis, scar revision, debulking of tumors, cysts, diagnostic biopsy and skin resurfacing.

Use of the device is further indicated for the incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971459

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)