DEC - 9 1997 K973576 ATTACHMENT A

510(k) SUMMARY

Epulse Er:aser™ Laser System

This 510(k) summary of safety and effectiveness for the Epulse Er:aser™ Laser System is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Epulse Technologies, Inc.
Address:	4838 Bentree Avenue Long Beach, CA 90807-1007
Contact Person:	Mr. Sanford Damasco VP Engineering and Chief Operating Officer 4838 Bentree Avenue Long Beach, CA 90807-1007
Telephone:	562-984-7729 562-984-0788 (Fax)
Preparation Date: (of the Summary)	August 1997
Device Trade Name:	Er:aser™ Laser System (Epulse Laser System)
Common Name:	Erbium: Yttrium, Aluminum; Garnet (Er:YAG) Laser System; Erbium Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code:	GEX; Panel 79.
Legally marketed predicate devices	Schwartz Electro-Optics, Inc, TriLase 2940 Erbium Laser, and Continuum Biomed, Inc., Multilite Erbium Laser System
Description of the Device	The Epulse laser is an erbium:YAG laser which emits its energy at 2.94 um. See below for additional specifications.
Intended Use of the Epulse laser:	The Epulse laser is intended for coagulation, vaporization, ablation, or cutting of soft tissue in dermatology and plastic surgery, including aesthetic surgery and skin resurfacing.

This intended use is the same or similar to that for the claimed predicate devices.

TriLase Laser: The SEO Medical TriLase 2940 is indicated for use in small and large joint Arthroscopy, including microdiscectomies, endoscopic procedures and general surgical procedures for cutting (incision/excision), vaporizing and coagulating soft tissues. All soft tissues encountered in surgical procedures are included in this indication, such as, but not limited to, skin, subcutaneous tissue, striated and smooth tissue, muscle, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties include dermatology, plastic surgery (emphasis added), general surgery, urology, gynecology, pulmonary surgery, gastroenterology, ENT, thoracic-surgery, oral & maxillofacial surgery, ophthalmology, and podiatry.

Multilite Laser: The Multilite laser information includes "*Cosmetic laser surgery*... [is] primarily restricted to applications in dermatology, plastic surgery, and *aesthetic surgery*." (emphasis added)

Performance Data: None. The specifications and intended uses of the Epulse laser are the same or very similar (substantially equivalent) to those of the claimed predicate devices. There are no significant differences between the devices under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION: The Epulse laser is substantially equivalent to legally marketed predicate devices, i.e., the Schwartz Electro-Optics, Inc. TriLase 2940 erbium laser (K954013) and the Continuum Biomed, Inc. Multilite - erbium laser system (K961748).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1997

Mr. Sanford Damasco
VP Engineering and Chief Operating Officer
Epulse Technologies, Inc.
4838 Bentree Avenue
Long Beach, California 90807-1007

Re: K973576
Trade Name: *Epulse* Model 2940 Er:aser™ Er:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: September 2, 1997
Received: September 19, 1997

Dear Mr. Damasco:

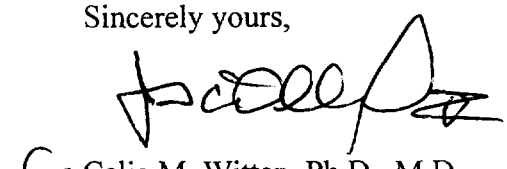
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for 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

ATTACHMENT D

510(K) Number: K973576

Device Name: Epulse Erbium Laser System (Er:aser™)

Indications For Use:

The Er:aser™ laser is intended for coagulation, ablation, vaporization, or cutting of soft tissue in dermatology and plastic surgery, including aesthetic surgery and skin resurfacing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Per 21 CFR 810.109)

OR

Over-The/Counter-Use

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973576