

K972915

DEC 19 1997

510(k) Summary Statement

Applicant: Phantom Technologies, Inc.
845 Commercial Avenue
Palo Alto, California 94303

Contact: James A. Nations
Phone: 415-493-9155
Fax: 415-493-9146

Device Name: Erbium 2000
Model A
Model B
Model C
Model D
Model E

Class of the device and panel: Class II
Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Performance Standards: UL544, UL2601.1, IEC601.1, IEC825
21 CFR 1040.10 & 1040.11

Reason for submission: New laser system family with
substantial equivalence.

Predicate Devices:

Pfizer	k904627
Pfizer	k905802
Schwartz Electro Optics	k954013
Coherent	k960032
Continuum Biomedical	k961748
Aesculap-Meditec	k964128
HGM	Unknown
Fotana/Candela	k962902
Laserscope	k964016
ESC Medical	k964532
Coherent	k963339
Coherent	k951812
Coherent	k912029
Laserscope	Unknown

Device Description:

Phantom Erbium lasers are composed of the following components:

- a laser console
- a counterbalanced articulated arm and handpiece
- a control / display panel
- a finger trigger or foot pedal control
- a laser head w/ beam optics
- a CPU control system
- a power supply
- an internal cooling system

Models range from 5 to 50 Watts average power.

Indications For Use:

The Erbium 2000 laser family is designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties and applications include: general surgery, plastic surgery, aesthetic surgery, dermatology, urology, gynecology, genitourinary, ENT, pulmonary surgery, thoracic surgery, podiatry, oral & maxillofacial surgery, ophthalmology (including oculoplasty), small and large joint arthroscopy, microdissectomies, and endoscopic procedures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Mr. James A. Nations
Director, Regulatory Affairs
Phantom Technologies, Incorporated
845 Commerical Avenue
Palo Alto, California 94303

Re: K972915
Trade Name: Erbium 2000 Laser Family, Models A, B, C, D, and E
Regulatory Class: II
Product Code: GEX
Dated: November 13, 1997
Received: November 19, 1997

Dear Mr. Nations:

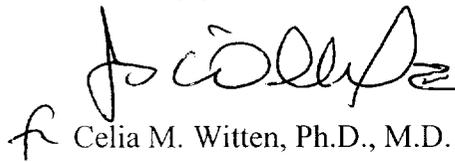
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,


f 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): K972915

Device Name: ERBIUM 2000 LASER FAMILY

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K972915

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)