

510(k) SUMMARY STATEMENT

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

Contact James A. Nations
Phone: 650-493-9155
Fax: 650-493-9146

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

**Establishment
Registration Number:** Applied for, not yet received

Device Name: ScanTech

Common Name: Laser accessory; scanner

Device Class: II
Instrument, laser accessory

Panel: 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 accessory with substantial
equivalence.

Product Description:

The Phantom ScanTech handpiece is intended to be used with the Phantom Family of Medical Lasers to deliver a broad spectrum of laser light energy for use in surgical applications generally requiring the ablation, vaporization, excision, incision and coagulation of soft tissue in a variety of medical specialties.

The Phantom ScanTech handpiece is composed of the following main components:

- Handpiece with dual galvo X - Y scanning capabilities
- Control / power cable
- Laser control / display panel interface
- CPU based Laser control system
- CPU controlled power supply
- Removable spatula-bayonet tip
- Screw ring attachment for articulated arm

Used in conjunction with the Phantom Family of Medical Lasers, the ScanTech scanning handpiece will provide a fully integrated,

automated scanning device to accurately and quickly apply computer-controlled patterns of various shapes and sizes. The Physician, or his/her assistant, will select the desired shape, size and density, as well as other operating parameters, from the Phantom laser's interactive touch screen.

Predicate Devices:	Coherent	k960032, k951812, k943604
	Clinicon	k962242
	Laserscope	k964520, k955734, k941841
	Sahar	k964684
	Sharplan	k961935, k960820, k960521, k955621

Indications For Use:

The ScanTech laser scanning handpiece is designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation and photo thermolysis of soft tissue in medical specialties including: general surgery, plastic surgery, aesthetic surgery, dermatology, ophthalmology including, but not limited to use in oculoplasty.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

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

Re: K974633
Trade Name: ScanTech Laser Scanner
Regulatory Class: II
Product Code: GEX
Dated: December 9, 1997
Received: December 12, 1997

Dear Mr. Nations

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.

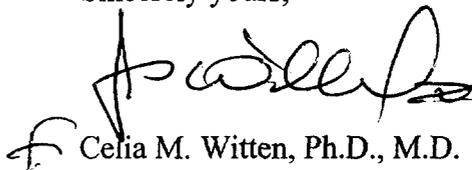
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K974633

DEVICE NAME: SCANTECH

INDICATIONS FOR USE:

The ScanTech laser scanning handpiece is designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation and photo thermolysis of soft tissue in medical specialties including: general surgery, plastic surgery, aesthetic surgery, dermatology, ophthalmology (limited to periorbital demis).

(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 801.109)

OR Over-The-Counter-Use _____
(Optional Format 1-2-96)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974633