SCITON K022381

OCT 18 2002

Attachment IV

510(k) Summary

Submitter:	Sciton, Inc.
Address:	845 Commercial Street, Palo Alto, CA 94303
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Contact Person:	Jay M. Patel, Director of Regulatory Affairs
Date Prepared:	July 15, 2002
Device Trade Name:	Profile 1320 Laser System
Common Name:	Nd:YAG Laser System
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	CoolTouch Nd:YAG Laser System (K002347)
Description of Profile 1320 Laser System:	Profile 1320 Laser System is an Nd:YAG laser producing emission at a wavelength of 1320 nm. It consists of a laser console, internal computer, control panel and display, an optical delivery system comprised of an articulated arm and a handpiece or scanner with cooling capability, and a footswitch.
Intended Use:	The Profile 1320 Laser System is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation, with hemostasis of soft tissue.
Rationale for Substantial Equivalence:	The Profile 1320 Laser System shares the same indications for use, similar design features (including wavelength, laser medium, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and is therefore substantially equivalent to the above legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Sciton, Inc.
Jay M. Patel
Director, Regulatory Affairs
845 Commercial Street
Palo Alto, California 94303

Re: K022381
Trade/Device Name: Profile 1320 Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 15, 2002
Received: July 22, 2002

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): K022381

Device Name: **Profile 1320 Laser System**

Indications for Use:

The Profile 1320 Laser System is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022381