JUN 13 2003

Attachment IV

510(k) Summary K023881

Submitter:	Sciton, Inc.
Address:	845 Commercial Street, Palo Alto, CA 94303
Phone:	(650) 493-9155
Fax :	(650) 493-9146
Contact Person:	Jay M. Patel, Director of Regulatory Affairs
Date Prepared:	November 18, 2002
Device Trade Name:	Profile 1064 Laser System
Common Name:	Nd:YAG Laser System
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	Sciton's laser systems (K002853, K003046 & K010285). Altus Medical Aesthetic Nd:YAG Lasers (K991234, K99l798, K003202 and K014040 and K022226); Lyra/Orion Laser Systems manufactured by Laserscope (K990718, K990903, K003147, K003765, K010284, K010834 and K020021); and VeinLase, manufactured by HGM (K981952).
Description of Profile Laser System:	Profile Laser System is an Nd:YAG laser producing emission at a wavelength of 1064nm. 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 1064 Laser Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

Dermatology:

Coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The Profile 1064 Laser Systems and Accessories are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Profile 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles.

The intended use of the contact cooling system in the Profile handpiece is to provide cooling of the skin prior to, during and after laser treatment, for the epidermal protection and reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:

Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

Rationale for Substantial Equivalence:	The Profile Laser System and Accessories share the same indications for use and technological characteristics and is therefore substantially equivalent according to 510(k) guidelines to the above legally marketed predicate devices.
Safety and Effectiveness Information:	The above indications for use are based upon the indications for use for predicate laser systems. The technological characteristics are identical to previous predicate Sciton's laser systems (K002853, K003046 & K010285). As a result, the risks and benefits are comparable to the predicate devices. We therefore conclude that there are no issues of safety or effectiveness raised by the introduction of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2003

Mr. Jay M. Patel
Director of QA/RA
Sciton, Inc.
845 Commercial Street
Palo Alto, California 94303

Re: K023881
Trade/Device Name: Profile 1064 Laser Systems and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 14, 2003
Received: March 17, 2003

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.

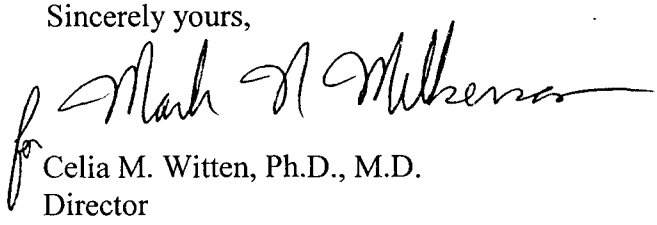
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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" (21CFR Part 807.97) you may obtain. 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,



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): K023981

Device Name: **Profile 1064 Laser Systems and Accessories**

Indications for Use:

The Profile 1064 Laser Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

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for Mark N. Milhorn

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023981

Surgical Applications:

Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023881