K081352

Attachment IV

510(k) Summary

OCT 23 2008

Submitter:	Sciton, Inc.
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Contact Person:	Jay M. Patel, VP of Regulatory Affairs
Date Prepared:	October 21, 2008
Device Trade Name:	Profile Multi-Platform System
Common Name:	Laser/Light Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	K070388: Profile Multi-Platform Laser System and Accessories K070805: ULTRAWAVE II EX 1320 K042474: ARION Laser System K034030: Cynosure Apogee Elite Laser K024371: GentleLASE Family of Laser Systems K024260: GentleLASE Family of Laser Systems K080121: Cynosure Smartlipo Multiwavelength Laser K072751: CoolTouch NS160 CoolLipo Nd:YAG Surgical Laser K072779: Ceralas D 980nm Diode Laser System (Models D15, D25)
Description of Profile Multi-Platform System	The Profile Multi-Platform System is a modular, multi-wavelength laser/light system. The system uses scanning and focusing optics to deliver a pattern of thermal energy to the treatment site. The system consists of control console which houses the power supply, cooling system, fiber optic delivery system and/or articulated arm delivery system with handpiece and/or scanner.
Intended Use:	**755 nm Indications for Use:** The 755 nm Profile Multi-Platform System with its accessories is indicated for stable long-term, or permanent hair reduction for all skin types (Fitzpatrick I - VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions and wrinkles. **1320 nm Indications for Use:** The 1320nm Profile Multi-Platform System with its accessories is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Profile 1320nm laser is further indicated for laser assisted lipolysis. **2940 nm Indications for Use:** The 2940 nm Profile Multi-Platform System with Profractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

Technological Characteristics	The Profile Multi-Platform System shares the same indications for use, similar design features (including wavelength, laser/light medium and delivery systems, 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 devices.
Safety and Effectiveness	The indications for use are based upon the indications for use for predicate systems. Technologically, the Profile Multi-Platform System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile Multi-Platform System are comparable to the predicate devices.
Conclusion	The Profile Multi-Platform System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sciton, Inc.
% Mr. Jay M. Patel
VP of Regulatory Affairs
925 Commercial Street
Palo Alto, California 94303

OCT 23 2008

Re: K081352
Trade/Device Name: Profile Multi-Platform System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 5, 2008
Received: September 5, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
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): K081352

Device Name: **Profile Multi-Platform System**

Indications for Use:

755 nm Indications for Use:

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1320 nm Indications for Use:

The 1320nm Profile Multi-Platform System with its accessories is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Profile 1320nm laser is further indicated for laser assisted lipolysis.

2940 nm Indications for Use:

The 2940 nm Profile Multi-Platform System with Profractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Blythe for MKM

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

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