NOV 1 3 2003

Attachment IV

K032460

510(k) Summary

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:	July 31, 2003
Device Trade Name:	Profile BBL System
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	Lumenis Family of Intense Pulsed-Light (KO30527, K020839) Palomar EsteLux (K020453) Altus Medical CoolGlide with Optional Pulsed Light Hand Piece (K023954)
Description of Profile BBL System:	Profile BBL System emits intense wide spectrum emission with wavelength of 500-1400 nm. It consists of a system console, internal computer, control panel and display, and a treatment head comprised of a light guide with cooling capability and a pushbutton switch.
Intended Use:	The Profile BBL (and the light and/or laser delivery accessories) is indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology. It is intended for use for: • The treatment of tattoos; • The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); • The treatment of cutaneous lesions including warts, scars and striae;

	• The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, engiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; • Treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis; and • The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction. The integral thermo-electric cooler is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to: • Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling); • Reduce discomfort during and/or associated with light or laser treatment; • Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation; • Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and • Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).
Rationale for Substantial Equivalence:	The Profile BBL 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 devices.
Safety and Effectiveness Information	The indications for use are based upon the indications for use for predicate systems. Technologically, the Profile BBL system is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile BBL system are comparable to the predicate devices.
Conclusion	The Profile BBL 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

NOV 13 2003

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

Re: K032460
Trade/Device Name: Profile BBL System
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: July 31, 2003
Received: August 16, 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. 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 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): **K032460**

Device Name: **Profile BBL System**

Indications for Use:

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It is intended for use for:

- The treatment of tattoos;
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- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, engiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- Treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis; and
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction.

The integral thermo-electric cooler is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

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

510(k) Number K032460