MAR 2 9 2004

K 040805

Attachment IV

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:	March 23, 2003
Device Trade Name:	Profile 2000 and Profile 3000 Laser Systems, and Delivery Devices and Accessories
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	Profile 2000 Equivalent Trimedyne Holmium Laser System Surgical Laser Technologies LaserPro CTH Holmium Laser System Lumenis VersaPulse Holmium and Dual Wavelength Surgical Lasers & Delivery Devices with Accessories New Star Holmium Laser System Profile 3000 Equivalent Erbium 2000 Laser Family FutureLase 3000/3002 Erbium Laser System Schwartz Electro-Optics CLR 2940 Erbium CrystaLase Laserscope VELA Erbium:YAG Laser System and Accessories
Description of Profile EV Laser System:	The Profile 2000 and Profile 3000 emits laser energy with wavelength of 2.01 µm and 2.94 µm respectively. The laser consists of a system console, internal computer, control panel and display, and a fiber optic delivery system and footswitch.
Intended Use:	The **Profile 2000 Laser System**, and Delivery Devices and Accessories, is indicated for incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an endoscope, in contact and non-contact with

tissue, with or without a hand piece, in the following indications:

Dermatology and Plastic Surgery
Dermatologic and Plastic Surgery of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasias [facial, leg] and rosacea), corns, papillomas, basal cell carcinomas, lesions of skin and subcutaneous tissue, plantar warts, periungual and subungual warts, debridement of decubitus ulcer, skin tag vaporization.

Gastroenterological/Gastrointestinal Surgery
Gastroenterologic surgery of soft tissue, including: cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery
General surgery of soft tissues, including; skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablations; removal of benign and malignant lesions; mastectomy, hepatectomy, pancreatectomy, splenectomy, thyroidectomy, parathyroidectomy, herniorrhaphy, tonsillectomy, lymphadenectomy, partial nephrectomy, pilonidal cystectomy, resection of lipoma, pelvic adhesiolysis, debridement of decubitus ulcer, hemorrhoids, pilonidal cyst removal and repair, debridement of statis ulcer, biopsy, appendectomy, pylorostenotomy, removal of polyps of the sigmoid colon, lysis of adhesions, cholecystectomy.

Genitourinary Surgery/Urology
Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions. Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and

resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecological Surgery
Gynecological surgery of soft tissue, including condyloma acuminata.

Lithotripsy and Percutaneous Urinary Lithotripsy
Lithotripsy and percutaneous urinary lithotripsy, including: fragmentation of urinary calculi, fragmentation of calculi in the ureter and ureteropelvic junction, fragmentation of kidney calculi, fragmentation of urethral calculi and treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Lumbar Discectomy
Lumbar discectomy in soft, cartilaginous and bony tissue, including: vaporization of the L.4-5 and L.5-S1 lumbar discs of the vertebral spine; open, percutaneous and endoscopic spine procedures; foraminotomy.

Orthopedic Surgery
Orthopedic surgery in soft and cartilaginous tissue in small and large joints (excluding the spine), including: knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, loose body debridement, capsulectomy in the knee, chondroplasty in the knee, chondromalacia ablation.

Otorhinolaryrigological (ENT) Surgery
Otorhinolaryrigological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangectasia, septoplasty.

Pulmonary Surgery
Open and endoscopic pulmonary surgery.

The **Profile 3000 Laser System**, and Delivery Devices and Accessories, is indicated for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, calculi or

	fragments, mucous membrane, lymph vessels and nodes, organs and glands. Aesthetic Surgery Skin resurfacing and treatment of wrinkles. Dermatology & Plastic Surgery Indications include, epidermal nevi, telangietasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitis ulcers. Gastroenterology General Surgery The Erbium:YAG laser is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation. Genitourinary/Urology Gynecology Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma. Ophthalmology Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy. Oral/Maxillofacial Otorhinolaryriqological (ENT) Surgery Podiatry Indications include warts, plantar verruae, large mosaic verrucae and matrixectomy. Pulmonary Surgery Thoracic Surgery
Rationale for Substantial Equivalence:	The Profile 2000 and Profile 3000 Laser Systems and Delivery Devices and Accessories share intended use, indications for use, similar design features (including wavelength, power supply, cooling and control system), functional features (including power output, repetition rate

	and pulse duration), and is therefore substantially equivalent to 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 2000 and Profile 3000 Laser Systems, and Delivery Devices and Accessories are substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile 2000 and Profile 3000 Laser Systems, and Delivery Devices and Accessories are comparable to the predicate devices.
Conclusion	The Profile 2000 and Profile 3000 Laser Systems, and Delivery Devices and Accessories, share similar indications for use, design features, and similar functional features as, and therefore are substantially equivalent to, the currently marketed predicate surgical lasers, delivery devices and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2004

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

Re: K040005
Trade/Device Name: Profile 2000 and Profile 3000 Laser Systems, and Delivery Devices 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: December 30, 2003
Received: January 7, 2004

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,

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): K040005

Device Name: Profile 2000 and Profile 3000 Laser Systems, and Delivery Devices and Accessories

Indications for Use:

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Gastroenterological/Gastrointestinal Surgery
Gastroenterologic surgery of soft tissue, including: cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

(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 K040005

General Surgery
General surgery of soft tissues, including; skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablations; removal of benign and malignant lesions; mastectomy, hepatectomy, pancreatectomy, splenectomy, thyroidectomy, parathyroidectomy, herniorrhaphy, tonsillectomy, lymphadenectomy, partial nephrectomy, pilonidal cystectomy, resection of lipoma, pelvic adhesiolysis, debridement of decubitus ulcer, hemorrhoids, pilonidal cyst removal and repair, debridement of statis ulcer, biopsy, appendectomy, pylorostenotomy, removal of polyps of the sigmoid colon, lysis of adhesions, cholecystectomy.

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Genitourinary surgery of soft tissue, including; treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions. Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

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Open and endoscopic pulmonary surgery.

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Aesthetic Surgery
Skin resurfacing and treatment of wrinkles.

Dermatology & Plastic Surgery
Indications include, epidermal nevi, telangietasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitis ulcers.

Gastroenterology

General Surgery
The Erbium:YAG laser is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation.

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Gynecology
Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Ophthalmology
Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Oral/Maxillofacial

Otorhinolaryrigological (ENT) Surgery

Podiatry
Indications include warts, plantar verruae, large mosaic verrucae and matrixectomy.

Pulmonary Surgery

Thoracic Surgery