K111493 Pg1 of 3

DEC - 7 2011

Attachment IV

510(k) Summary

Submitter:	Sciton, Inc.
Address:	925 Commercial Street, Palo Alto, CA 94303
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Contact Person:	Jay M. Patel, VP of Regulatory Affairs
Date Prepared:	September 26, 2011
Device Trade Name:	JOULE ClearSense Laser System
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification:	Regulation Number: 21 CFR 878.4810 Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology Regulatory Class: Class II Product Code: GEX
Legally Marketed Predicate Device:	K103626: Cutera GenesisPlus Laser System K093547: PinPointe FootLaser K093545: PinPointe FootLaser
Description of JOULE ClearSense Laser System:	The JOULE ClearSense Laser System is a transportable medical device used for the treatment of temporary increase in clear nail in patients with onychomycosis. It uses Nd:YAG laser with a wavelength of 1064 nm. ClearSense uses the laser energy to heat the target to a temperature that is sufficient to destroy it, but not to the point that the heat damages skin and surrounding tissue. The ClearSense system consists of a control console, a foot switch, articulated arm and a handpiece with a stainless steel guide tip (spacer) attached at its end. Control Console houses the power supply, control electronics, cooling system and optics to direct the laser beam to the input of the articulated arm. The following specifications list significant physical and performance characteristics of this device:

Laser Medium	Nd:YAG
Laser Wavelength	1064 nm
Energy per Pulse	20 - 3500 mJ
Max Power	≤ 100 W
Spot Size	1 mm
Output Mode	Pulsed
Aiming Beam Wavelength	630 - 680 nm
Aiming Beam Power	≤ 2.5 mW

Rated Voltage	200-240 V~
Rated Frequency	50/60 Hz
Rated Current	25 A
Classification	Class I, Type BF
Laser Output	Class IV

Intended Use:

The JOULE ClearSense Laser System is indicated for ablation, vaporization, incision, excision and coagulation of soft tissue, including:

- Matrixectomy
- Periungual and subengual warts
- Planter warts
- Radical nail excision
- Neuromas

It is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum and T. mentegrophytes*, and/or yeasts *Candida albicans, etc.).*

Technological Characteristics:

The JOULE ClearSense Laser System shares the same indications for use, and as noted below, shares similar design features (including wavelength, laser 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.

Specification	JOULE ClearSense Laser System	Cutera GenesisPlus Laser	PinPointe FootLaser
Ref. 510(k)	K111483	K103626	K093547, K093545
Wavelength	1064 nm Nd:YAG	1064 nm Nd:YAG	1064 nm Nd:YAG
Aiming Beam	630 - 680 nm (≤ 2.5 mW)	630 - 680 nm (≤ 2.5 mW)	630 - 680 nm (≤ 2.5 mW)
Energy per Pulse	20 - 3500 mJ	20 - 3500 mJ	20 - 3500 mJ
Fluence	25.5 J/cm2	25.5 J/cm2	25.5 J/cm2
Max Power	≤ 100 W	≤ 100 W	≤ 100 W
Pulse Duration	100 - 3000 µsec	100 - 3000 µsec	100 - 3000 µsec
Spot Size	1 mm* (up to 13 mm for other indications)	1 mm* (up to 13 mm for other indications)	1 mm* (other spot sizes not published)
Output Mode	Pulsed, multimode	Pulsed, multimode	Pulsed, multimode
Repetition Rate	5 - 100 Hz	5 - 100 Hz	5 - 100 Hz
Laser Media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
User Interface	LCD touchscreen	LCD touchscreen	LCD touchscreen

* for increase in clear nail

Safety and Effectiveness:

The indications for use are based upon the indications for use for predicate systems. Technologically, the JOULE ClearSense Laser System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE ClearSense Laser System are comparable to the predicate devices.

Conclusion: The JOULE ClearSense Laser 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

MAY 13 2013

Re: K111483
Trade/Device Name: JOULE ClearSense Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: November 21, 2011
Received: December 01, 2011

Dear Mr. Patel:

This letter corrects our substantially equivalent letter of December 07, 2011.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): K111483 Pg 1 of 1

Device Name: JOULE ClearSense Laser System

Indications for Use:

The JOULE ClearSense Laser System is indicated for ablation, vaporization, incision, excision and coagulation of soft tissue, including:

- Matrixectomy
- Periungual and subengual warts
- Planter warts
- Radical nail excision
- Neuromas

It is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum and T. mentagrophytes*, and/or yeasts *Candida albicans, etc.)*.

Neil R. P. Ogden for mac

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111483

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)