Attachment IV

510(k) Summary

Submitter: Sciton, Inc.
Address: 925 Commercial Street, Palo Alto, CA 94303
Phone: (650) 493-9155
Fax: (650) 493-9146
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:

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Medium</td>
<td>Nd:YAG</td>
</tr>
<tr>
<td>Laser Wavelength</td>
<td>1064 nm</td>
</tr>
<tr>
<td>Energy per Pulse</td>
<td>20 - 3500 mJ</td>
</tr>
<tr>
<td>Max Power</td>
<td>≤ 100 W</td>
</tr>
<tr>
<td>Spot Size</td>
<td>1 mm</td>
</tr>
<tr>
<td>Output Mode</td>
<td>Pulsed</td>
</tr>
<tr>
<td>Aiming Beam Wavelength</td>
<td>630 - 680 nm</td>
</tr>
<tr>
<td>Aiming Beam Power</td>
<td>≤ 2.5 mW</td>
</tr>
</tbody>
</table>

Page 1 of 3
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 subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

It is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dematophytes *Trichophyton rubrum* and *T. mentagrophytes*, 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.

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

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

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

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
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- 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.).

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

510(k) Number K111483

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)