K101916

MAR 18 2011

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:	March 16, 2011
Device Trade Name:	JOULE 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:	**755 nm Laser System** K081352: Profile Multi -Platform System **Q-Switched 755 nm Alex** K081324: Candela Family of Q-Switched Alexandrite K072868: Cynosure Accolade II Laser **1064 nm Laser System** K070388: Profile Multi-Platform System K060033: Profile Multi-Platform System K023881: Profile 1064 Laser System **Q-Switched 1064/532 nm Nd:YAG** K083899: Hoya ConBio RevLite Q-Switched Nd:YAG Laser System K072564: Alma Harmony XL Multi-Platform Q-Switched Nd:YAG K050382: Cynosure Affinity QS Q-Switched Nd:YAG Laser System **1319 nm Laser System** K081352: Sciton Profile Multi-Platform System K070388: Sciton Profile Multi-Platform System K060033: Sciton Profile Multi-Platform System **1470 nm Laser System** K083613: Quanta System Polysurge Diode Laser Family K082230: Xintec Vectra Family of Laser Systems and Accessories K082225: Biolitec Ceralas D 1470 nm Diode Laser **1470 nm Laser System (Fractional)** K101506: Palomar Lux 1440 K090195: Palomar Lux1540 K070284: Reliant Technologies Fraxel SR1500 Laser System **1550 nm Laser System (Fractional)** K090195: Palomar Lux1540 K070284: Reliant Technologies Fraxel SR1500 Laser System **2940 nm Laser System (Fractional)** K081352: Sciton Profile Multi-Platform System K070388: Profile Multi-Platform System K060033: Profile Multi-Platform System K100270: Palomar LUX2940 **BBL System** K070388: Sciton Profile Multi-Platform System K060033: Sciton Profile Multi-Platform System K042165: Cutera Titan K042630: RevLight Skin Care System

Description of JOULE Multi-Platform System:	The JOULE 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:	**The 755 nm Alexandrite system is designed for use in:** The ClearScan ALX 755nm Alexandrite laser 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. **Q-Switched 755 nm Alexandrite Indications for Use:** The JOULE Q-Switched 755 nm Alex Multi-Platform Systems with accessories are indicated for the following uses: Pigmented Lesions Tattoos **The 1064 nm Nd:YAG Indications for Use:** Coagulation and hemostasis of benign vascular lesions such as, but not limited to, telangiectasias and rosacea. Removal of unwanted hair (for stable, long term or permanent hair reduction) through selective targeting of melanin in hair follicles and for the treatment of Pseudofolliculitis Barbae (PFB). Treatment of facial wrinkles. The JOULE 1064 nm Nd:YAG with fiber delivery is indicated for laser assisted lipolysis. **Q-Switched 1064/532 nm Nd: YAG Indications for Use:** The JOULE Q-Switched 1064/532 nm Nd:YAG Multi-Platform Systems with accessories are indicated for the following uses: Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis. Specific Indications: *1064 nm wavelength* Tattoo Removal (dark ink: blue and black) Nevus of Ota Removal or lightening of hair with or without adjuvant preparation Skin Resurfacing for Acne Scars and Wrinkles Benign Cutaneous Lesions, such as, but not limited to: striae and scars Reduction of Red Pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. *532 nm wavelength* Tattoo Removal (light ink: yellow, red, light blue, green) Vascular Lesions including but not limited to: port wine stains/birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi Epidermal Pigmented Lesions including but not limited to: Cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus Other Pigmented Cutaneous Lesions including verrucae, skin tags, keratoses and plaques Skin Resurfacing for Acne Scars and Wrinkles Benign Cutaneous Lesions, such as, but not limited to: striae and scars

Reduction of Red Pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The 1319 nm Nd:YAG Indications for Use:

Treatment of fine lines and wrinkles.
Treatment of atrophic acne scars.
Treatment of mild to moderate inflammatory acne vulgaris.
The JOULE 1319 nm Nd:YAG with fiber delivery is indicated for laser assisted lipolysis.
The JOULE 1319 nm Nd:YAG with fiber delivery is indicated for the treatment of reflux of great and small saphenous veins associated with varicose veins and varicosities, and for treatment of incompetence and reflux of superficial veins in the lower extremity.

1470 nm Indications for Use:

The JOULE 1470 nm Multi-Platform Systems and delivery accessories are intended for delivery of laser light to soft tissue for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

The JOULE 1470 nm Multi-Platform Systems with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

1550 nm Indications for Use:

The JOULE 1550 nm Multi-Platform Systems with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

2940 nm Indications for Use:

The JOULE 2940 nm Multi-Platform Systems with delivery accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing.
Aesthetic Surgery: Skin resurfacing and treatment of wrinkles.
Dermatology & Plastic Surgery: Indications include epidermal nevi, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, and decubitis ulcers. It is also used for laser assisted site preparation for hair transplantation.

The JOULE 2940 nm Multi-Platform Systems with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing, and ablation and coagulation of soft tissue.

BBL (300-1400nm) Indications for Use:

The Joule Multi-Platform Systems and Accessories are 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:

- Mild to moderate inflammatory and pustular inflammatory acne vulgaris.
  (420nm BP filter, 515nm LP filter, 560 LP filter)
- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
  (515nm LP filter, 560nm LP filter)
- The treatment of cutaneous lesions including warts, scars and striae;
  (515nm LP filter, 560nm LP filter)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias,

rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; *(560nm LP filter, 590nm LP filter)*

- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction *(590nm LP filter, 640nm LP filter, 695 LP filter)*
- Topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain. *(800 nm LP filter)*

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).

Technological Characteristics:	The JOULE 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 JOULE Multi-Platform System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE Multi-Platform System are comparable to the predicate devices.
Conclusion:	The JOULE 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAR 18 2011

Re: K101916
Trade/Device Name: JOULE Multi-Platform 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: GEX, ONG, ORK, ONF
Dated: March 17, 2011
Received: March 17, 2011

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. 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.

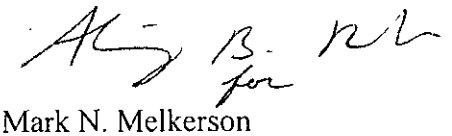
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): **K101916**

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

Indications for Use:

The 755 nm Alexandrite system is designed for use in:

The ClearScan ALX 755nm Alexandrite laser 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.

Q-Switched 755 nm Alexandrite Indications for Use:

The JOULE Q-Switched 755 nm Alex Multi-Platform Systems with accessories are indicated for the following uses:
Pigmented Lesions
Tattoos

The 1064 nm Nd:YAG Indications for Use:

Coagulation and hemostasis of benign vascular lesions such as, but not limited to, telangiectasias and rosacea.
Removal of unwanted hair (for stable, long term or permanent hair reduction) through selective targeting of melanin in hair follicles and for the treatment of Pseudofolliculitis Barbae (PFB).
Treatment of facial wrinkles.
The JOULE 1064 nm Nd:YAG with fiber delivery is indicated for laser assisted lipolysis.

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)

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

510(k) Number K101916

Q-Switched 1064/532 nm Nd: YAG Indications for Use:

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Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

Specific Indications:

1064 nm wavelength

Tattoo Removal (dark ink: blue and black)
Nevus of Ota
Removal or lightening of hair with or without adjuvant preparation
Skin Resurfacing for Acne Scars and Wrinkles
Benign Cutaneous Lesions, such as, but not limited to: striae and scars
Reduction of Red Pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

532 nm wavelength

Tattoo Removal (light ink: yellow, red, light blue, green)
Vascular Lesions including but not limited to: port wine stains/birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
Epidermal Pigmented Lesions including but not limited to: Cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus
Other Pigmented Cutaneous Lesions including verrucae, skin tags, keratoses and plaques
Skin Resurfacing for Acne Scars and Wrinkles
Benign Cutaneous Lesions, such as, but not limited to: striae and scars
Reduction of Red Pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

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Treatment of fine lines and wrinkles.
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1470 nm Indications for Use:

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1550 nm Indications for Use:

The JOULE 1550 nm Multi-Platform Systems with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

2940 nm Indications for Use:

The JOULE 2940 nm Multi-Platform Systems with delivery accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Aesthetic Surgery: Skin resurfacing and treatment of wrinkles. Dermatology & Plastic Surgery: Indications include epidermal nevi, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, and decubitis ulcers. It is also used for laser assisted site preparation for hair transplantation.

The JOULE 2940 nm Multi-Platform Systems with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing, and ablation and coagulation of soft tissue.

Mark R Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
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510(k) Number K101916

Prescription Use X OR Over-The-Counter Use _____
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BBL (300-1400nm) Indications for Use:

The JOULE Multi-Platform Systems and Accessories are 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:

- Mild to moderate inflammatory and pustular inflammatory acne vulgaris.
  (420nm BP filter, 515nm LP filter, 560 LP filter)
- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
  (515nm LP filter, 560nm LP filter)
- The treatment of cutaneous lesions including warts, scars and striae;
  (515nm LP filter, 560nm LP filter)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
  (560nm LP filter, 590nm LP filter)
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction
  (590nm LP filter, 640nm LP filter, 695 LP filter)
- Topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
  (800 nm LP Filter)

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);

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510(k) Number K101916

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).

Neil R. Ogden for MKN

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

510(k) Number K101916

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