



Food and Drug Administration
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Silver Spring, MD 20993-0002

Quanta System SPA
Mr. Francesco Dell' Antonio
Compliance Manager
Via IV Novembre, 116
Solbiate Olona (VA)
Italy, 21058

October 27, 2015

Re: K151629

Trade/Device Name: Guardian 1000

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, ILY, PDZ

Dated: September 25, 2015

Received: September 28, 2015

Dear Mr. Dell' Antonio:

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 Parts 801 and 809)]; 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)
K151629

Device Name
Guardian 1000

Indications for Use (*Describe*)

Guardian 1000 with its delivery accessories is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

Guardian 1000 with its delivery accessories is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, neurosurgery, general surgery, genitourinary surgery (urology), thoracic surgery, gynecology, pulmonology, ophthalmology, orthopedics, otolaryngology (ENT) and podiatry.

Gastroenterology

Hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis in colonoscopy.

Neurosurgery

Tumors adjacent to the spinal cord; tumors adjacent to the cortex.

General Surgery

Ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include but are not limited to: Laparoscopic: appendectomy, cholecystectomy, bowel resection. Open: mastectomy, reduction mammoplasty, breast biopsy, rectal and anal hemorrhoidectomy, bowel resection, colectomy, cholecystectomy, liver resection, condyloma, thyroidectomy, thoracotomy; cavernous hemangioma.

Genitourinary (Urology)

Transurethral: transurethral incision of the prostate (TUIP), bladder tumors, bladder neck incisions, urethral strictures, exterior sphincterotomy, laparoscopic lymphadenectomy. Open: condyloma, circumcision, benign and malignant lesions of external genitalia.

Thoracic Surgery

Pulmonary resection, coagulation of blebs and bullae, adhesiolysis, pericardiectomy, mediastinal and thoracic lesions and abnormalities, mediastinal lymph node dissection, hemostasis; thoracotomy.

Gynecology (GYN)

Laparoscopic excision/lysis of adhesions, endometrial lesions, including ablation of endometriosis, laparoscopic assisted hysterectomy (LAVH), laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy, ovarian drilling, tubal fimbrioplasty, appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN, condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

Pulmonology

Tracheal bronchial lesions.

Ophthalmology

Oculoplastics, open DCR, endo-nasal DCR, tumor excision and biopsy, eyelid reconstruction; blepharoplasty.

Orthopedics

Dissect and coagulate.

Otolaryngology (ENT)

Nasal/Sinus: turbinectomy and turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy;

Laryngo-tracheal: removal of vocal cord/ fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis;

Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy;

Head & Neck: tumor resection on oral, sub facial and neck tissues; parathyroidectomy; thyroidectomy.

Podiatry

Matrixectomy, Periungual and subungual warts, Plantar warts, Neuromas.

Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T mentagrophytes*, and /or yeasts *Candida albicans*, etc.).

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

Introduction:

This document contains the 510(k) Summary for the Guardian 1000 laser device. The content of this summary is based on the requirements of 21 CFR 807.92(c).

**Applicant /
Manufacturer
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Solbiate Olona (VA)
Italy, 21058

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Date Prepared: June 4th 2015

Device Name: Guardian 1000

Classification: Class II

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.

Regulation Number: 21 CFR 878.4810

Product Code: GEX, ILY, PDZ

Predicate Devices:

Guardian 1000 is substantially equivalent to the following legally marketed predicate devices:

- K110375 Gold Series - Blueshine srl (Italy)
- K101893 Nexus 30- USA Laser Biotech Inc. (USA)

Description of the device:

Guardian 1000 delivers an invisible laser beam in the infrared spectrum at 980 nm using a gallium aluminum arsenide (GaAlAs) source. The laser light beam is carried to the focusing lens on the handpiece probe by quartz optical fibers.

Guardian 1000 consists of two main sub-systems: a laser console and its delivery accessories, as follows:

The laser console includes:

- an external enclosure
- power electronics
- touch screen display with control electronics which controls:
 - o power electronics
 - o user interface
 - o laser source temperature
 - o laser source emission
- a laser system including:
 - o laser source
 - o cooling system (Peltier cells, dissipator and fans)
 - o fiber launching system
 - o aiming beam

Laser radiation is delivered to the patient through an optical fiber and several handpieces depending on the treatment.

The optical fiber is connected to the laser unit through a SMA905 connector .

Intended use

Guardian 1000 with its delivery accessories is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

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Comparison of Technological Characteristics:

Guardian 1000 has the same technological characteristics (energy source, laser source, control mechanism) and specifications as its predicate devices.

Performance data:

The following performance data are provided in support of the substantial equivalence determination:

Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Guardian 1000 device and its delivery accessories.

The system complies with the IEC 60601-1, IEC 60601-2-22 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The Guardian 1000 device is capable of achieving therapeutic temperature range of 40 - 45 degrees centigrade as accepted by the FDA. An increase in topical heating of the tissue level by at least 5 degrees centigrade was reached within one (1) minute as demonstrated in the bench testing. The therapeutic temperature range was maintained for over 10 minutes testing time. The temperatures versus time measurements were conducted on 3 subjects at 2 physical locations (shoulder and knee areas). The pre-exposed topical skin temperature ranged from 31.8 to 34.3 centigrade degrees. The topical temperature during exposure following brief stabilization time ranged from 40.8 to 43.9 centigrade degrees. These data demonstrate the System meets the generally accepted topical temperature range for therapeutic heat of 40 - 45 degrees centigrade during the recommended treatment time of 10 minutes.

Comparison of Intended Use:

Guardian 1000 device's Intended Use combines the Intended Uses of its predicate devices.

Substantial Equivalence:

The Guardian 1000 device and its delivery system is as safe and effective as its predicate devices.

The Guardian 1000 device and its delivery system has the same intended use, technological characteristics and specifications as its predicate devices.

Thus, Guardian 1000 device and its delivery system is substantially equivalent to its predicate devices.