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VII 510(k) Summary

SEP 24 2012

Title: Sheaumann Laser PL-1064

Submitter: Sheaumann Laser, Inc.
45 Bartlett Street
Marlborough, MA 01752

Contact: Timothy J. Shea
Vice President, Sheaumann Laser, Inc.
189 Winding Oaks Lane
Oviedo, Fl 32765
Phone: 407) 590-2050
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Date Prepared: March 5, 2012

Device Trade Name: Sheaumann Laser PL-1064

Common Name: Laser instrument for use in podiatry, dermatology and plastic surgery.

Classification Name: Instrument, surgical, powered laser
GEX
21 CFR 878.4810

Predicate Device: PathoLase PinPointe Foot Laser (K093547)

Device Description: The Sheaumann PL-1064 is a medical grade, solid-state, infrared diode laser (AlGaAs). The laser is designed to deliver continuous or pulsed, infrared laser energy with a wavelength at 1064 nm. The touch screen display consists of a user interactive screens that allows selection of continuous, pulsed and the TMP/CLEAR NAIL/ Clear Nail modes of operation, repetition rates, aiming beam on/off, procedural information display keys, a Standby/Ready key, the manual emergency stop button and the master key switch.

THE LASER SYSTEM: The laser system consists of a laser diode optical deck, cooling system, voltage power supply and system control electronics that include the touch screen control panel.

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The mail console: Contains major electrical components.

DELIVERY SYSTEM: The reusable 1.0 mm collimated handpiece has been designed to deliver a spot size of 1.0 mm. Safety glasses/goggles and a safety sign are also provided with the PL-1064.

Intended Use: Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

* Plantar warts
* Periungual and subungual warts

Sheaumann PL-1064 is seeking indication for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermiatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans, etc.).*

Comparison: The Sheaumann PL-1064 is an extremely similar device as the PathoLase PinPointe FootLaser (K093584), the safety and effectiveness of the PL-1064 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of the medical devices.

Summary: From a design and clinical perspective, the predicate and candidate laser device, are the same technology and have the same intended use. Based upon the fact that the devices are extremely similar, the PL-1064 should not raise any concerns regarding its overall safety and/or effectiveness.

Non clinical Performance Data: None

Clinical Performance Data: None

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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

May 13, 2013

Sheaumann Laser, Incorporated
% Mr. Timothy J. Shea
Vice President
189 Winding Oaks Lane
Oviedo, Florida 32765

Re: K120938
Trade/Device Name: PL-1064
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: August 07, 2012
Received: August 13, 2012

Dear Mr. Shea:

This letter corrects our substantially equivalent letter of September 24, 2012.

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 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

Indications for Use

510(k) Number: K120938

Device Name: PL-1064

Indications for Use

The PL-1064 laser, collimated handpiece will be indicated for ablation, vaporizing, excision, incision, and coagulation of soft tissue encountered in dermatology, plastic surgery, and podiatry including but not limited to plantar warts, periungual and subungual warts and telangiectasia. .

The PL-1064 will also be indicated for the temporary increase of clear nail in patients with onychomycosis (e.g., derniatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans, etc.)*.

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

510(k) Number K120938

Prescription Use [X] AND/OR Over-the-counter [ ]

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)