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510(k) Summary

FEB 1 1 2013

1. Submission Sponsor

Convergent Dental, Inc.
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2. Submission Correspondent

Emergo Group
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Contact: Carrie Hetrick, Senior Consultant
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3. Date Prepared

23 October 2012

4. Device Identification

Trade/Proprietary Name:	Solea
Common/Usual Name:	CO_2 laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and dermatology
Classification Regulation:	878.4810
Product Code:	GEX
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Predicate Devices

Lutronic Corporation Spectra DENTA II Laser System, 510(k) Number: K091320

6. Device Description

The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy to cut soft tissue in the oral cavity. The Solea system utilizes advanced CO_2 laser technology with a wavelength of 9.25µm to safely and effectively perform incision, excision, vaporization, coagulation, and hemostasis.

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7. Intended Use

The Solea system is indicated for the following:

- Incision
- Excision
- Vaporization
- Coagulation
- Hemostasis

of soft tissue in the oral cavity.

8. Comparison of Technological Characteristics

The following table compares the Solea to the predicate device with respect to the intended use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

	Convergent Dental, Inc.	**Lutronic Corporation**
Trade Name	Solea	Spectra DENTA II
510(k) Number	Pending	K091320
Common Name	CO_2 Laser	CO_2 Laser
Classification Names (FDA)	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument
FDA Classification Codes	GEX	GEX
Predicates cited	K091320	K050254, K030147, K935563, K963229, K991297, K021508, K081181
Target User	General practitioner dentists and specialists	General practitioner dentists and specialists
Indications for use	The Solea system is indicated for the following: • Incision • Excision • Vaporization • Coagulation • Hemostasis of soft tissue in the oral cavity.	The Spectra DENTA II Laser System is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and

	Convergent Dental, Inc.	Lutronic Corporation
Trade Name	Solea	Spectra DENTA II
		excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.
Laser classification	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product
Type of Laser	CO_2 (Carbon Dioxide)	CO_2 (Carbon Dioxide)
Wavelength	9.25µm (9250 nm)	10.6µm (10600 nm)
Fluence: Energy per mm^2	1.13J/mm^2	1.08J/mm^2
Irradiance: Power per mm^2	112.80W/mm^2	194.80W/mm^2
Operating Modes	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous
Beam Delivery	Articulating Arm (Free Space)	Articulating Arm (Free Space)
Sterilization Methods	Steam Autoclave	Steam Autoclave
RF emissions	CISPR 11 Group 1	CISPR 11 Group 1
EMC compliance	CISPR 11 Class A	CISPR 11 Class A
Harmonic emissions	IEC 61000-3-2 Class A	IEC 61000-3-2 Class A
Voltage fluctuations/ flicker emissions	IEC 61000-3-3	IEC 61000-3-3 Class A

9. Non-Clinical Performance Data

The Solea system meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety. The results of the non-clinical testing confirm the output meets the design inputs and specifications. Bench testing was performed to demonstrate substantial equivalence to the predicate device in terms of safety and performance. The following non-clinical testing was performed:

- **Electrical Safety Testing:**
  The system passed electrical safety testing in accordance with requirements for medical electrical equipment.
- **Electromagnetic Compatibility:**
  The system passed electromagnetic compatibility (EMC) testing to meet requirements for medical electrical equipment.

- **Laser Safety:**
  The system passed particular requirements for the safety of diagnostic and therapeutic laser equipment.
- **Cleaning and Sterilization:**
  The handpieces of the Solea system passed cleaning and sterilization validations for reusable medical devices.
- **Software:**
  Verification testing was conducted on the Solea software. All tests were completed successfully with respect to stated pass/fail criteria thereby deeming the device and software appropriate for its intended use.
- **Usability:**
  Usability testing was conducted on the Solea system. Based on the participant feedback and ratings of usability of the Solea system, all of the acceptance criteria for the user design validation have been met for the intended use.
- **Bench Testing: Solea Soft Tissue Testing:**
  Performance data was collected using the Solea system and the predicate device. A quantitative analysis was conducted evaluating the depth, width and length of cuts, a histological assessment of changes in sample tissue, and effect on tissue surrounding the incision areas. The results show substantially equivalent results for both systems.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The nonclinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The Solea device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the Solea system and the predicate devices do not raise any questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Solea system is substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. Solea, as designed and manufactured, is determined to be substantially equivalent to the referenced 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

Convergent Dental, Incorporated
% Emergo Group, Incorporated
Ms. Carrie Hetrick
Senior Regulatory Consultant
611 West 5th Street
Third Floor
Austin, Texas 78701

February 11, 2013

Re: K123494
Trade/Device Name: Solea
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
Dated: November 05, 2012
Received: November 13, 2012

Dear Mr. Hetrick:

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,

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 Statement

510(k) Number (if known): K123494

Device Name: Solea

Indications for Use:

The Solea system is indicated for the following:

- Incision
- Excision
- Vaporization
- Coagulation
- Hemostasis

of soft tissue in the oral cavity.

Prescription Use	AND/OR	Over-The-Counter Use _____
__X_____		(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)		

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.02.11 13:12:15 -05'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K123494_____