JUL 1 2 2013

Section 5 – 510(k) Summary for Solea

1. Submission Sponsor

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3. **Date Prepared**
June 28, 2013

4. Device Name

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
Classification Panel: General and Plastic Surgery
Product Code: GEX
Device Class: II

FDA Establishment Registration #: 10043517

5. Predicate Devices

Convergent Dental, Inc., Solea, 510(k) Number: K123494
Biolase Technology, Inc., Waterlase MD, 510(k) Number: K091746
Fotona d.d., LightWalker Laser System, 510(k) Number: K101817

6. Device Description

The Solea system is a dental laser device previously cleared by the FDA for soft tissue dental indications (K123494). The only changes from the previously cleared device are the addition of the hard tissue indications, which combines minor software and graphic changes that will be added to the Solea system. This software change does not change the operational software, but adds a material selection icon on the home screen to include enamel, dentin, and soft tissue. The enamel and dentin settings have substantially equivalent fluence and irradiation as the hard tissue predicate devices. There are no other hardware or software changes to the Solea system device pending herein when compared to the device cleared under K123494.

The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy to cut and ablate hard tissue and 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 ablation, incision, excision, vaporization, coagulation and hemostasis procedures.

7. Intended Use

The Solea system is indicated for the following:

- Ablation of hard tissue for caries removal and cavity preparation.
- Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.

8. Technological Characteristics and Substantial Equivalence

The following table compares the Convergent Dental, Inc. Solea system to the Biolase Technology Inc. Waterlase MD, Fotona d.d. LightWalker Laser System Family with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence for intended uses.

The Solea system is substantially equivalent for hard tissue intended use in terms of fluence, irradiance, measured comparative performance data, and all features that affect safety or effectiveness to the Biolase Technology, Inc. Waterlase MD (K091746) and the Fotona d.d., LightWalker Laser System (K101817). For soft tissue indications, the Solea system included herein is the same device that was previously cleared by the FDA as the Convergent Dental, Inc. Solea system (K123494).

	Convergent Dental, Inc.	**Convergent Dental, Inc.**	**Biolase Technology, Inc.**	**Fotona d.d.**
Trade Name	Solea	Solea	Waterlase® MD	LightWalker Laser System Family
510(k) Number	K130420	K123494	K091746	K101817
Common name	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument
FDA Classification Names	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument Drill, bone, powered	Powered Laser surgical instrument

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
			System, Dental, Hydrokinetic, Carries Removal & Cavity Preparation	
FDA Classification codes	GEX, a Class II device	GEX, a Class II device	GEX, MXF, DZI, a Class II device	GEX, a Class II device
Predicates cited	K091746, K101817 for hard tissue indications K123494 for soft tissue indications	K091320 for soft tissue indications	K031140, K071363, K090181 for hard tissue indications	K093162 for hard tissue indications
Target User	General practitioner dentists and specialists	General practitioner dentists and specialists	General practitioner dentists and specialists	General practitioner dentists and specialists
Indications for Use	The Solea system is indicated for the following: - Ablation of hard tissue for caries removal and cavity preparation. - Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.	The Solea system is indicated for the following: - Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.	General Indications* Class I, II, III, IV and V cavity preparation Caries removal Hard tissue surface roughening or etching Enameloplasty, excavation of pits and fissures for placement of sealants* * For use on adult and pediatric patients Root Canal Hard Tissue Indications Tooth preparation to obtain access to root canal Root canal preparation including enlargement Root canal debridement and cleaning Root Canal Disinfection Laser root canal disinfection after endodontic instrumentation Bone Surgical	The LightWalker Er:YAG laser, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures: In dentistry, for: - Intra-oral soft tissue surgery (incision, excision, ablation coagulation) - Leukoplakia - Pulpotomy as adjunct to root canal retreatment - Pulp extirpation - Removal of fibromae - Removal of granulated tissue - Caries removal, cavity preparation, enamel

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
			Indications Cutting, shaving, contouring and resection of oral osseous tissues (bone) Osteotomy Endodontic Surgery (Root Amputation) Indications Flap preparation – incision of soft tissue to prepare a flap and expose the bone. Cutting bone to prepare a window access to the apex (apices) of the root(s). Apicoectomy – amputation of the root end. Root end preparation for retrofill amalgam or composite. Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation. Soft Tissue Indications including Pulpal Tissues* Incision, excision, vaporization, ablation and coagulation of oral soft tissues,	roughening - Sulcular debridement - Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root - canal preparation including enlargement - Cutting, shaving, contouring and resection of oral osseous tissue (bone) - Osteotomy, osseous crown lengthening, osteoplasty - Apicectomy surgery. Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
			including: Excisional and incisional biopsies Exposure of unerupted teeth Fibroma removal Flap preparation – incision of soft tissue to prepare a flap and expose the bone. Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions) Frenectomy and frenotomy Gingival troughing for crown impressions Gingivectomy Gingival incision and excision Hemostasis Implant recovery Incision and drainage of abscesses Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery Leukoplakia Operculectomy Oral papillectomies Pulpotomy Pulp extirpation Pulpotomy as an adjunct to root canal therapy Root canal debridement and cleaning Reduction of gingival hypertrophy Removal of pathological tissues	

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
			(i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation. Soft tissue crown lengthening Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa Vestibuloplasty Laser Periodontal Procedures Full thickness flap Partial thickness flap Split thickness flap Laser soft tissue curettage Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium Removal of granulation tissue from bony defects Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve	

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
			clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility) Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours) Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.) Osseous crown lengthening Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium). Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.	
Laser classification	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product
Type of Laser	CO_2 (Carbon Dioxide)	CO_2 (Carbon Dioxide)	Er,Cr:YSGG (Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet)	Er:YAG (Erbium: Yttrium, Aluminum, Garnet) Nd:YAG (Neodymium-doped: Yttrium, Aluminum, Garnet)
Wavelength	9.25µm (9250nm)	9.25µm (9250nm)	2.78µm (2780nm)	Er:YAG = 2.94µm (2940nm)

	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				Nd:YAG = 1.064µm (1064nm)
Fluence: Energy per mm^2 (per pulse)	0.01 – 0.3 J/mm^2 (hard tissue) 0.1 – 2 J/mm^2 (soft tissue)	0.1 – 2 J/mm^2 (soft tissue)	-	-
Repetition Rate per second (Hz)	1000-2200 Hz (hard tissue) 20-100 Hz (soft tissue)	20-100Hz (soft tissue)	-	-
Irradiance: Power per mm^2	2 – 264 W/mm^2 (hard tissue) 2-170 W/mm^2 (soft tissue)	2-170 W/mm^2 (soft tissue)	-	-
Operating Modes	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous
Beam Delivery	Articulating Arm (Free Space)	Articulating Arm (Free Space)	Fiber	Articulating Arm (Free Space)
Sterilization Method	Steam Autoclave	Steam Autoclave	Steam Autoclave	Steam Autoclave
RF emissions	CISPR 11 Group 1	CISPR 11 Group 1	CISPR 11 Group 1	CISPR 11 Group 1
EMC compliance	CISPR 11 Class A	CISPR 11 Class A	CISPR 11 Class A	CISPR 11 Class A

9. Non-Clinical Testing

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 IEC 60601-1 medical electrical equipment.
- **Electromagnetic Compatibility:**
  The system passed electromagnetic compatibility (EMC) testing to meet requirements for IEC 60601-1-2 medical electrical equipment.
- **Laser Safety:**
  The system passed particular requirements for IEC 60601-2-22 and IEC 60825-1 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 based on the overkill approach to demonstrate sterilization cycle lethality as described in AAMI TIR12 to achieve a Sterility Assurance Level (SAL) of at least 10-6. The Solea system handpieces are designed for sterilization by exposure to moist heat under conventional autoclave cycles qualified to ANSI/AAMI ST79.

- **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. During the usability evaluation, dentists used the system to perform procedures on simulated tissues in a laboratory environment that replicates the intended deployment environment of the dental office. 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 Hard Tissue Testing:**
  Performance data was collected from Bench Testing for hard tissue. Results show that hard tissue thermal effects are equivalent. The results show substantially equivalent results for the Solea system and the two predicate systems.

10. Clinical Testing

An *in-vivo* study was conducted at the UCSF School of Dentistry to evaluate the pulpal effects of enamel ablation using a pulsed CO_2 laser at a wavelength of 9.3µm. The fundamental science and design of the laser system used for this UCSF research is substantially equivalent to the Solea system. The purpose of the study was to determine if heat disposition in the tooth may have any detrimental pulpal effects under the conditions required for small conservative preparations confined to enamel. Histological examination of pulp immediately after extraction showed no deleterious effects on pulpal tissues and none of the test-subjects felt pain or discomfort after the procedure. The results show that the technology of the Solea system is safe for the intended uses.

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 20993-002

July 12, 2013

Convergent Dental, Inc.
% Emergo Group, Inc.
Ms. Carrie Hetrick, DDS
611 West 5th Street, Third Floor
Austin, Texas 78701

Re: K130420
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: May 08, 2013
Received: May 09, 2013

Dear Dr. 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,

Mark N. Melkerson -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): K130420

Device Name: Solea

Indications for Use:
The Solea system is indicated for the following:

- Ablation of hard tissue for caries removal and cavity preparation.
- Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.07.12 08:49:51 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130420