September 14, 2022

Convergent Dental, Inc.
Jhung Vojir
Chief Operating Officer
140 Kendrick Street
Needham, Massachusetts 02494

Re: K221761
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: NVK, GEX
Dated: June 16, 2022
Received: June 17, 2022

Dear Jhung Vojir:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.,
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221761

Device Name
Solea

Indications for Use *(Describe)*

The Solea system is indicated for the following:

- Ablation of hard tissue for caries removal and cavity prevention
- Incision, excision, vaporization, coagulation and hemostasis of soft tissue in the oral cavity
- Cutting, shaving, contouring and resection of oral osseous tissue (both)
- Aiding in the reduction of mineral loss in dental enamel

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K221761

510(k) SUMMARY

Convergent Dental, Inc.
Solea

510(k) Owner
Convergent Dental, Inc.
140 Kendrick Street, Bldg C3
Needham, MA 02494, USA

Contact person:
Jhung Won Vojir, PhD
Chief Operating Officer
Email: jvojir@convergentdental.com

Date Prepared: June 16, 2022

Trade Name of Device
Solea

Common or Usual Name
Powered laser surgical instrument

Classification Name
Laser surgical instrument for use in general and plastic surgery and dermatology;
21 C.F.R. §878.4810
Class II
Product Code: GEX

Predicate Device
Convergent Dental, Inc. Solea cleared in K151306 (Primary Predicate)

Device Description
The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy for ablation of hard tissue for caries removal and cavity preparation; incision, excision, vaporization, coagulation, and hemostasis of soft tissue in the oral cavity; cutting, shaving, contouring and resection of oral osseous tissue (bone). The Solea system utilizes CO_2 laser technology with a wavelength of 9.3 μm.

The modification to the cleared Solea system is the introduction of the DR Handpiece which allows the system to deliver controlled sub-ablative energy necessary to heat the tooth surface mineral without ablation for the new treatment of aiding in the reduction of mineral loss in the tooth enamel.

The Solea system will be used in the same way it is used for the currently cleared indications for use. The user will select the desired operating mode from the user interface and apply the energy via a handpiece in the same method as used for the previously cleared indications.

Indications for Use

The Solea system is indicated for:

- Ablation of hard tissue for caries removal and cavity preparation
- Incision, excision, vaporization, coagulation and hemostasis of soft tissue in the oral cavity
- Cutting, shaving, contouring and resection of oral osseous (bone)
- Aiding in the reduction of mineral loss in dental enamel

Substantial Equivalence

Convergent Dental believes that the Solea described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device which is the Solea cleared in K151306. The table below compares the properties of the two devices.

Solea Substantial Equivalence

Characteristic	Solea	Solea	Comments
Manufacturer	Convergent Dental	Convergent Dental	Same
510(k) Number	K221761	K151306	Same
Product Code	GEX	GEX	Same
Regulation	21 CFR 878.4810	21 CFR 878.4810	Same
Intended Use	For use in dental and oral laser surgery	For use in dental and oral laser surgery	Same
Indications for Use	• Ablation of hard tissue for caries removal and cavity preparation • Incision, excision, vaporization, coagulation and hemostasis of soft tissue in the oral cavity • Cutting, shaving, contouring and resection of oral osseous (bone) • Aiding in the reduction of mineral loss in dental enamel	• Ablation of hard tissue for caries removal and cavity preparation • Incision, excision, vaporization, coagulation and hemostasis of soft tissue in the oral cavity • Cutting, shaving, contouring and resection of oral osseous (bone)	Same with the exception of adding the reduction in mineral loss in dental enamel. Performance data is provided which supports substantial equivalence.
Clearance Type	Prescription	Prescription	Same
User	Healthcare Professional	Healthcare Professional	Same
Device Description	The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy to cut and ablate hard and soft tissue in the oral cavity. The Solea system	The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy to cut and ablate hard and soft tissue in the oral cavity. The Solea system	Same

	utilizes advanced CO2 laser technology with a wavelength of 9.25µm to safely and effectively perform ablation, incision, excision, vaporization, coagulation and hemostasis.	utilizes advanced CO2 laser technology with a wavelength of 9.25µm to safely and effectively perform ablation, incision, excision, vaporization, coagulation and hemostasis.	
Laser Source	CO_2	CO_2	Same
Mode	Single	Single	Same
Laser Wavelength	9.25 µm	9.25 µm	Same
Frequency	Up to 10KHz (hard tissue) 20 to 100 Hz (soft tissue)	Up to 10KHz (hard tissue) 20 to 100 Hz (soft tissue)	Same
Max Peak Power Output	1 KW	1 KW	Same
Average Power	0 to 30 W	0 to 30 W	Same
Power Accuracy	+/- 20%	+/- 20%	Same
Max Pulse Energy	15 mJ (hard tissue) 100 mJ (soft tissue)	15 mJ (hard tissue) 100 mJ (soft tissue)	Same
Pulse Duration	5-90 us (hard tissue) 10-250 us (soft tissue)	5-90 us (hard tissue) 10-250 us (soft tissue)	Same
Aiming Beam	520nm diode 5mW (Safety classification 3R)	520-535 nm diode 5mW (Safety classification 3R)	Substantially equivalent
Fluence Energy per mm^2	0.008 J/mm^2 (mineral loss reduction) 0.39 J/mm^2 (hard tissue) 1.13 J/mm^2 (soft tissue) 2.0 J/mm^2	0.39 J/mm^2 (hard tissue) 1.13 J/mm^2 (soft tissue) 2.0 J/mm^2	New low fluence mode added for reduction in mineral loss. All other modes are the same as the predicate device.
Operating Modes	Ablation laser : Pulsed Aiming laser : Continuous	Ablation laser : Pulsed Aiming laser : Continuous	Same
Beam Delivery	Articulating Arm (Free space)	Articulating Arm (Free space)	Same
Sterilization Methods	Steam Autoclave	Steam Autoclave	Same
RF Emissions	CISPR 11 Group 1	CISPR 11 Group 1	Same
RF Emissions	CISPR 11 Class A	CISPR 11 Class A	Same

The intended use of the Solea as well as the predicate device Solea is for use in dental and oral surgery. The indications for use have been revised to add "aiding in the reduction of mineral loss in dental enamel". Both devices are mobile, cart-based dental treatment systems that use pulsed laser energy to cut and ablate hard and soft tissue in the oral cavity. Both systems use CO_2 laser technology with 9.25 µm wavelength. Key treatment parameters such as max pulse energy, frequency and pulse duration are unchanged between the Solea cleared in K151306 and the version that is the subject of this 510(k).

The device modifications proposed in this supplement are for a device with similar mechanism of action and method of use as the cleared version of the device but with significantly lower energy delivered which reduces the overall risk profile compared to the currently cleared device. An assessment of risks found that risks are minimal compared to the currently cleared version of the Solea system.

Data demonstrate substantial equivalence regarding increase in pulpal temperature and other structural changes to the tooth such as melting, charring or carbonization. The in vitro studies found that the increase in pulpal temperature following the procedure was less than the maximum threshold of 5.5^0 C and there were no visually observed structural changes such as melting, charring or carbonization.
In conclusion, given the available information, for the proposed addition to the indications for use statement of "for aiding in the reduction of mineral loss in dental enamel", can be found substantially equivalent to the predicate device.

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 devices 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 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 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 and validation 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.

- **Bench Testing:**

In vitro testing demonstrated a significant benefit of the Solea system in aiding in the reduction of mineral loss in dental enamel as measured by the relative mineral loss in depth and surface

mineral loss, without significant damage to the enamel. Additionally, inhibition of surface softening and surface loss during pH cycling was observed.

Conclusion

Based on the substantial equivalence discussion and the performance testing, the Solea system is substantially equivalent to the Solea system cleared in K151306.