SECTION 5

JUL 25 2014

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

Submitter:
Den-Mat Holdings, LLC.
1017 West Central Ave.
Lompoc, CA 93436, USA
Tel. (805) 346-3700

Contact Person:
Robert Wang, *RAC*
Regulatory Affairs Manager
Tel.: (805) 346-3700 Ext. 3767
(805) 346-3767 Direct
Fax: (805) 347-7940
E-mail: rwang@denmat.com

Date Summary Prepared: April 11, 2014

2. Name of device, including the trade name and classification name:

Trade/Proprietary Name: *SOL Portable Diode Laser Unit (with wireless foot control)*

Common Name: *Powered laser surgical instrument*

Device Classification Name:	**Regulation Number**	**Class**	**Product Code**
Laser surgical instrument for use in general and plastic surgery and in dermatology.	*878.4810*	II	GEX

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Den-Mat Holdings, LLC
Device:	Sapphire ST Portable Diode Laser
510(k):	K103667
Date Cleared:	December 29, 2010

Company:	Discus Dental, LLC
Device:	SL3
510(k):	K102639
Date Cleared:	December 01, 2010

4. A description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The *SOL Portable Diode Laser Unit (with wireless foot control)* has the same intended use and indications for use as the Sapphire Portable Diode Laser (K103667). It is an alternate construction, incorporating the same principles of operation in a more ergonomic industrial design package. The SOL Portable Diode Laser, or SOL, is a battery operated counter top dental surgical and therapeutic diode laser. The SOL comprises five main assemblies; a housing, an optical fiber with hand piece, and optical fiber "tip", a foot switch and an auxiliary power supply. The housing contains the system PCBs with system display, battery, control panel with indicators, auxiliary power and footswitch jacks, safety key switch, system power On/Off switch, diode laser with 808 nm working beam and 405 nm aiming beam, heat dissipation assembly with over temperature thermistor and fiber storage wrap. The optical fiber with hand piece comprises a single glass core fiber contained inside an outer PVC jacket, connectors for diode and tip coupling and a hand piece for precise delivery of laser energy to the target tissue. The optical fiber tip is a single patient disposable glass core fiber for delivery of laser energy to the target that couples to the hand piece fiber. A wireless foot control can be used to activate the laser working beam. The auxiliary power supply connects to the housing and is used to charge the system battery and as a power source for the diode laser in the event of low battery capacity.

5. Statement of intended use:

The *SOL Portable Diode Laser Unit (with wireless foot control)* is a medical electrical device intended for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fiber optic delivery system.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The proposed SOL Portable Diode Laser Unit (with wireless foot control) has the following technological similarities to the predicate devices:

- the equivalent working beam wavelength,
- the equivalent pulse control – digital emission control,
- the same laser source – solid state diode,
- the equivalent user interface, and
- the equivalent wireless foot control

7. Statement of how the functional characteristics of the device compare to those of the predicate or legally marketed device:

The proposed SOL Portable Diode Laser Unit (with wireless foot control) has the following functional similarities to the predicate devices:

- the equivalent indications for use,
- the same operating principle,
- the same basic construction,
- the same shelf life, and
- the same packaging materials and processes.

8. Comparative Performance Data:

The *SOL Portable Diode Laser Unit (with wireless foot control)* has been tested side-by-side against two of the predicate devices. Measurements of the output of the subject devices' working beam range from 0.1 to 3.0W output in Continuous Wave and Pulse modes were shown to vary from the unit's settings by an average of only 1.4% in CW and 0.5% in P compared to the predicate's variance of 2.2% in CW and 2.7% in P. The intended performance of these devices, based on IEC 60601-2-22, is that laser output should vary from the device's setting by less than ± 20% of the setting. Both the subject and predicate devices have been shown to satisfy this standard, with the subject device demonstrating less variability (more control) than the cleared predicate devices.

9. Technological Characteristics

Device Name	SOL Portable Diode Laser Unit (with wireless foot control) (Subject Device)	Sapphire ST Portable Diode Laser (Predicate Device)	SL3 (Predicate Device)
Manufacturer	DenMat Holding, LLC	DenMat Holding, LLC	Discus Dental, LLC
510(k) Number	KXXXXXX	K103667	K102639
Wavelength	808 ±5 nm	808 ±5 nm	808 ±10 nm
Power	3 Watts	3 Watts	3 Watts
Aiming Bean	405 ±10 nm, max. 5 mW	640 nm ±10 nm, max. 2 mW	650 nm, max. 5 mW
Cooling System	Convection cooled	Convection cooled	Convection cooled
Pulse Control	Digital emission control	Digital emission control	Unknown
Laser Source	Solid-state diode	Solid-state diode	Solid-state diode
Power Requirements	24W 5VDC supplied from 110-120 VCA @ 60 Hz or 220 – 240 VAC @ 50 Hz (switchable)	24W 5VDC supplied from 110-120 VCA @ 60 Hz or 220 – 240 VAC @ 50 Hz (switchable)	100 - 240 VAC, 50 - 60 Hz
User Interface	Membrane touch pad, LCD Display, LED Indicators	Membrane touch pad, LCD Display, LED Indicators	LCD Touch screen
Fiberoptic Tip	Disposable, 400 um Unit dose	Disposable, 400 um Unit dose	Unknown

10. Conclusions:

The *SOL Portable Diode Laser Unit (with wireless foot control)* has the equivalent indications for use and technological characteristics as that of the predicate devices. The minor technological and material differences exist between the SOL Portable Diode Laser Unit (with wireless foot control) and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the SOL Portable Diode Laser Unit (with wireless foot control) is as safe, as effective, and performs as well as or better than the DenMat, *Sapphire ST Portable Diode Laser* (K103667) and Discus Dental, *SL3* (K102639). Therefore, it can be concluded that the SOL Portable Diode Laser Unit (with wireless foot control) is substantially equivalent to the 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

July 25, 2014

Den-Mat Holdings, LLC
Mr. Robert Wang, RAC
Regulatory Affairs Manager
1017 West Central Avenue
Lompac, California 93436

Re: K141838
Trade/Device Name: SOL Portable Diode Laser Unit (with wireless foot control)
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: July 8, 2014
Received: July 10, 2014

Dear Mr. Wang:

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 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,

David Krause -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141838

Device Name

SOL Portable Diode Laser Unit (with wireless foot control)

Indications for Use *(Describe)*

The SOL Portable Diode Laser Unit (with wireless foot control) is intended for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fiber optic delivery system. Indications include excision and incision biopsies; hemostatic assistance; treatment of apthous ulcers; frenectomy; frenotomy; gingival incision and excision; gingivectomy; gingivoplasty; incising and draining abscesses; operculectomy; oral papillectomy; removal of fibromas; soft tissue crown lengthening; sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket); tissue retraction for impression; vestibuloplasty.

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)*

Neil R Ogden -S
2014.07.24 16:19:36 -04'00'

For BSA

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."