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

September 26, 2016

Viax Dental Lab
Mr. Edwin First
Regulatory Affairs Consultant
Calle Potrerillos, Flexipark Bodegas D2
Alajuela, San Rafael
Cost Rica 20108

Re: K161185
Trade/Device Name: VIAX Dental Lab LUCERNA VDL 980-1
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 24, 2016
Received: August 24, 2016

Dear Mr. First:

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 Part 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 Parts 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" (21 CFR 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,

Christopher J. Ronk -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)*
K161185

Device Name
VIAX Dental Lab LUCERNA VDL980-1

Indications for Use *(Describe)*
The VIAX Dental Lab LUCERNA VDL980-1 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. The following are the indications for which the device will be marketed:

. 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
. Photo initiation of gingival barriers and dams
. Laser-assisted bleaching/whitening of teeth

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.

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."

510(k) Summary of Safety and Effectiveness

VIAX Dental Lab VIAX DENTAL LAB LUCERNA VDL980-1

Submitted for: Viax Dental Lab,

Phone: 949-633-3554
Facsimile: (888) 557-7207
Contact Person: Edwin First
Date Prepared: 20 April 2016

Device Proprietary Name(s): VIAX DENTAL LAB LUCERNA VDL980-1 Dental Laser
Common or Usual Name: General Dental Use Soft tissue and Curing Laser
Product Classification: Powered Laser Surgical Instrument
Product Code: GEX
Predicate Device(s): (1) Biolase EPIC soft tissue Laser (2) ILT Systems ACL 5500 Argon Curing Laser(3) Denmat Sapphire ST Portable

Rationale for Substantial Equivalence

Both the subject and predicate devices share similar intended uses and indications for use, technical characteristics, features, and specifications. The Laser characteristics of the VIAX Dental Lab LUCERNA VDL980-1, including working wavelengths and outputs, Light delivery methods, safety features, and performance specifications are similar to those of the cleared *Biolase Epic, ILT ACL5500, and Denmat Sapphire ST Portable* Dental Lasers. The VIAX Dental Lab LUCERNA VDL980-1 operating system and controls of the subject device are similar to those used by the previously-cleared predicate devices that have proven safety and effectiveness records in the treatment of the claimed indications. Safety and performance test results have been shown to satisfy applicable international standards recognized by the Agency.

Intended Uses and Indications for Use

The VIAX Dental Lab LUCERNA VDL980-1 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. The following are the indications for which the device will be marketed:

- 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
- Photo initiation of gingival barriers and dams
- Laser-assisted bleaching/whitening of teeth

Device Description

The VIAX Dental Lab LUCERNA VDL980-1 Portable Diode Laser is comprised of three basic parts: The control box ("control module") with microprocessor and user interface for selection of modes: (a) Procedural (continuous wave or pulsed) 980nm laser output (b) Curing (dental photo initiated materials) at 450nm (+/-10nm) with timed outputs of 1,3, and 5 second(s) of output duration; and (c) Whitening procedures at 450nm (+/-10nm) timed to provide 15 minute durational output(s); A touch screen LCD display to provide visual indications of power settings and of the unit"s status, and accept inputs via the touch screen to select modes and operational parameters and adjust / set and features the units power ON/OFF functions, Application of user PIN number for operation and initialization, Selection of Language (English, Spanish, Portugese) and System settings (PIN/Password setting); the Second component is the laser handpiece that houses the laser working beam and aiming beam fiber optic component(s) and the disposable fiberoptic tip assemblies (Procedural, Curing, and Whitening). Two optional footswitches are available that can be used to activate the laser working beam: (a) Corded that plugs into the back of the system unit and (optional) wireless footswitch. Electrical power is taken from the AC/DC 12 vdc Power Supply that plugs into a standard electrical outlet and charges the L-ion 7.2VDC battery at 24W, a 7,2 VDC lithium-ion battery that generates 4 amps used to drive the diode laser(s) and system overhead.

Conformity to International Standards

The VIAX Dental Lab LUCERNA VDL980-1 Portable Diode Laser complies with the performance requirements listed in 21 CFR 1040.10 and 1040.11, with permissible deviations pursuant to Laser Notice 50, dated July 26, 2001. Additionally, the subject device has been shown to conform to the same international electrical safety standards for electrical medical devices in general, and lasers in particular, as the predicate devices: IEC 60601-1, IEC 60601-2-2, IEC 60825-1, and IEC 60601-2-22.

Comparative Performance Data

The VIAX Dental Lab LUCERNA VDL980-1 Portable Diode Laser has been tested side-by-side against one of the predicate devices. Measurements of the output of the subject device's working beam ranging from 0.1 to 3.0W output in Continuous Wave and Pulse modes were shown to vary from the VIAX Dental Lab LUCERNA VDL980-1 settings by an average of only 1.4% in CW and 0.5% in P(ulse) compared to the predicate's variance of 2.2% in CW and 2.7% in P(ulse). 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.

Comparison of Features and Characteristics

Table 1, following, lists key Features and Characteristics of the subject and three predicate devices.

Table 1.

	VIAX Dental Lab VIAX Dental Lab LUCERNA VDL980-1	**Biolase EPIC Portable Dental Laser**	**ILT ACL5500 Dental Curing Laser**	**Denmat Holdings Sapphire ST Portable Laser**
Application	Dental Laser (Multi Function)	Dental Laser (Multi Function)	Curing Laser	Dental Laser
Wavelength	980nm ±10nm	980 ±5 nm	450 ±20 nm	808 ±5 nm
Power	0.1 – 3.0 W (CW) 0.1 – 5.0 W (Pulse	0.1 – 3.0 W (CW) 0.1 – 5.0 W (Pulse)	500mW	0.1 – 3.0 W (CW) 0.1 – 5.0 W (Pulse)
Aiming Beam	640 nm (±10nm), maximum 2mW (adjustable)	640 nm (±10 nm), maximum 2mW (adjustable)	N/A	640 nm (±10 nm), maximum 2mW (adjustable)
Cooling System	Convection cooled	Convection cooled	FAN forced air	Convection Cooled
Pulse Control	Digital emission Contr ol	Digital emission control	N/A	Digital emission control
Laser Source	Solid-state diode	Solid-state diode	Argon Ion	Solid State Diode
Power Requirements	24W 12VDC supplied from 110 - 120 VAC @ 60 Hz or 220 - 240 VAC @ 50 Hz (switchable)		100-240VAC @ 50-60 Hz, (switchable)	24W 12VDC supplied from 110 - 120 VAC @ 60 Hz or 220 - 240 VAC @ 50 Hz (switchable)
User Interface	LCD Touch Screen Interface	LCD Touch Screen Interface	Discreet switches	Membrane touch pad,LED indicators

Fiberoptic Tip	Disposable, 200 µm unit dose	Disposable, 200µm unit dose	Optic/mirror via 400um fiber optic	Disposable, 400 µm unit dose
Sterility	Disposable, Barrier sleeve	Disposable, Barrier sleeve	Disposable, Barrier sleeve	Disposable, Barrier sleeve
510(k) Number	**Pending this application**	K140120	K930210	K103667

Conclusion

The subject device shares the same principle of operation as the three predicate devices. All are diode lasers that emit radiant energy at approximately 808nm to 980nm and 450nm with outputs that range from 0.1 to 5.0W. All deliver collimated laser energy to subject target tissue via 200 to 400 µm fiberoptic tips controlled by trained, experienced clinicians. All share the same indications for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. All have photo initiated dental teeth whitening, and one other has dental materials curing. All have been found to satisfy international safety standards relating to electrical medical devices in general and medical lasers in particular. All have similar safety labeling, device interlocks, and associated safety features. Both the subject and a predicate devices output were measured and compared to their settings to determine the accuracy of the devices‟ controls. Both met international standards pertaining to accuracy of output of the working beam, but the difference between the subject devices output and its setting was much less than the predicate's, demonstrating not only conformance to the standard, but also superior control over laser emissions. Performance testing has been accomplished for the Viax Dental Lab Lucerna VDL980-1that compares it to the predicate devices and that it meets international standards pertinent to validating its performance and compliance. The Viax Dental Lab Lucerna VDL980-1 has been tested and is in compliance with IEC60601-1 (Medical Electrical Equipment Safety); IEC60601-1-2 (EMC): IEC60825-1/IEC60601-2-22 (Photobiological Safety); Software validation in compliance with IEC61508; and ISO 14971 (Risk Management).

The VIAX Dental Lab LUCERNA VDL980-1

Viax Dental Lab Lucerna VDL980-1 device shares intended uses, principle of operation, technical attributes, functional capabilities, and performance characteristics with the listed predicate devices. Both the subject and predicate devices have been shown to comply with applicable Federal and international safety and performance standards. The Sapphire ST Portable Laser is substantially equivalent to the listed predicate laser surgical devices and does not raise any issues of safety or effectiveness.