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 21, 2016

CAO Group, Inc.
Mr. Robert K. Larsen
Regulatory Affairs Manager
4628 West Skyhawk Drive
West Jordan, UT 84084

Re: K160413
Trade/Device Name: Sterling 5W Diode Laser
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: August 22, 2016
Received: August 24, 2016

Dear Mr. Larsen:

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" (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,

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)*
K160413

Device Name
Sterling Diode Laser

Indications for Use *(Describe)*
The Sterling Diode Laser is indicated for:
Dental soft tissue indications:

Dental, oral and soft tissue surgery including:
Sulcular debridement of diseased or fibrous tissue, excision and biopsy, gingivectomy and gingivoplasty, lesion (tumor) removal, fibroma removal, tissue retraction (troughing), aphthous ulcers, gingival hyperplasia (excision and recontour), crown lengthening, operculectomy, frenectomy, and photocoagulation.

Laser periodontal procedures, including:
Laser soft tissue curettage; laser removal of diseased, infected and necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

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)

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West Jordan, UT 84084 877.877.9778 [toll free]
www.caogroup.com 801.256.9287 [fax]

510(k) Summary

Prepared By: Robert K. Larsen
Preparation Date: August 22, 2016

Device Name:

Trade Name:	Sterling Diode Laser
Common Name:	Soft Tissue Diode Laser
Product Code:	GEX
Regulation:	878.4810
Product Classification:	Powered Laser Surgical Instrument Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Odyssey 2.4G Diode Laser, manufactured for Ivoclar Vivadent, Inc. (K050453)

Rationale for Substantial Equivalence:
The submitted device and identified predicate device share exactly identical indications for use:
Dental soft tissue indications:

Dental, oral and soft tissue surgery including:
Sulcular debridement of diseased or fibrous tissue, excision and biopsy, gingivectomy and gingivoplasty, lesion (tumor) removal, fibroma removal, tissue retraction (troughing), aphthous ulcers, gingival hyperplasia (excision and recontour), crown lengthening, operculectomy, frenectomy, and photocoagulation.

Laser periodontal procedures, including:
Laser soft tissue curettage; laser removal of diseased, infected and necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

Description of Submitted Device:

The Sterling Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 10nm for a maximum of 5 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The target tissues absorb the laser energy converting it to heat. depending on the intensity or power output of the laser, the heat so generated can cell hemostasis, ablation, or vaporization. The device features

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some user definable settings, including a selectable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.
The optical fiber is stored within the device and dispensed to the desired length according to the clinician's need. A fiber is passed through a reusable, sterilizeable handpiece assembly and terminated with a single-use disposable tip. The operator uses the handpiece to position and direct the laser energy to the intended treatment site. The activation of the working beam diodes is accomplished by use of a foot-actuated switch.

Description of the Predicate Device:

The Odyssey 2.4G Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 5 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The target tissues absorb the laser energy converting it to heat. depending on the intensity or power output of the laser, the heat so generated can cell hemostasis, ablation, or vaporization. The device features some user definable settings, including a selectable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.
The optical fiber is stored within the device and dispensed to the desired length according to the clinician's need. A fiber is passed through a reusable, sterilizeable handpiece assembly and terminated with a single-use disposable tip. The operator uses the handpiece to position and direct the laser energy to the intended treatment site. The activation of the working beam diodes is accomplished by use of a foot-actuated switch.

Indications for Use of the Submitted Device:

The submitted device is indicated for use for -
Dental soft tissue indications:

Dental, oral and soft tissue surgery including:
Sulcular debridement of diseased or fibrous tissue, excision and biopsy, gingivectomy and gingivoplasty, lesion (tumor) removal, fibroma removal, tissue retraction (troughing), aphthous ulcers, gingival hyperplasia (excision and recontour), crown lengthening, operculectomy, frenectomy, and photocoagulation.

Laser periodontal procedures, including:
Laser soft tissue curettage; laser removal of diseased, infected and necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

Technological Characteristics and Substantial Equivalence:

	CAO Group, Inc. Sterling Diode Laser	**Ivoclar Vivadent, Inc. Odyssey 2.4G**
Working Beam Output Power	810±10 nm	810±20 nm

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	CAO Group, Inc. Sterling Diode Laser	Ivoclar Vivadent, Inc. Odyssey 2.4G
Working Beam Output Wavelength	0.5 - 5.0 watts	0.1 - 5.0 watts
Aiming Beam Output Power	< 3mW	< 3mW
Aiming Beam Output Wavelength	630-650 nm	630-650 nm
Laser Source	AlGaAs Diode	AlGaAs Diode
Laser Activation	Wireless foot pedal	Wireless foot pedal
Pulse Control	Digital emission control Fixed pulse duration of 0.05 seconds, 10Hz	Digital emission control Fixed pulse duration of 0.05 seconds, 10Hz
Cooling Method	Heatsink / Fan air cooled	Heatsink / Fan air cooled
Electrical Power Input (System)	100-240 VAC @ 47-63 Hz, 1.5A (switchable)	100-240 VAC @ 47-63 Hz, 1.6A (switchable)
User Interface	Illuminated LED Display; Membrane keypad	Illuminated LED Display; Membrane keypad
Laser Delivery System	Quartz optical fiber	Quartz optical fiber
Dimensions	9” x 6” x 5”	10” x 8” x 4”
Weight	5.0 lbs	6.5 lbs (Control unit only)
510(k) Number	Pending this application.	K050453
Indications for Use	Dental soft tissue indications: Dental, oral and soft tissue surgery including: Sulcular debridement of diseased or fibrous tissue, excision and biopsy, gingivectomy and gingivoplasty, lesion (tumor) removal, fibroma removal, tissue retraction (troughing), aphthous ulcers, gingival hyperplasia (excision and recontour), crown lengthening, operculectomy, frenectomy, and photocoagulation. Laser periodontal procedures, including: Laser soft tissue curettage; laser removal of diseased, infected and necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by	Dental soft tissue indications: Dental, oral and soft tissue surgery including: Sulcular debridement of diseased or fibrous tissue, excision and biopsy, gingivectomy and gingivoplasty, lesion (tumor) removal, fibroma removal, tissue retraction (troughing), aphthous ulcers, gingival hyperplasia (excision and recontour), crown lengthening, operculectomy, frenectomy, and photocoagulation. Laser periodontal procedures, including: Laser soft tissue curettage; laser removal of diseased, infected and necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by

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	CAO Group, Inc. Sterling Diode Laser	Ivoclar Vivadent, Inc. Odyssey 2.4G
	bacteria penetration of the pocket lining and junctional epithelium.	bacteria penetration of the pocket lining and junctional epithelium.

Conformity to Standards:

The Sterling Diode Laser is designed to comply with the performance requirements of ANSI/AAMI ES60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2006, IEC 60601-2-22:2007, and IEC 60825-1:2007.

Performance Data:

Bench testing on an evaluation sample of the submitted device was performed consistent with internal requirements:

- QAC-P02265 - Final assembly inspection of Sterling Diode Laser
- Sterling 5W Main and Safety Specification Verification Test

Conclusion:

The Sterling 5W Diode Laser is substantially equivalent to the listed predicate. This device shares identical intended uses, identical operating principles, similar design features, and identical functional and performance characteristics.