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 22, 2017

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

Re: K171986
Trade/Device Name: Sterling Supreme 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, ILY
Dated: June 26, 2017
Received: July 3, 2017

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 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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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)*

K171986

Device Name
Sterling Supreme Diode Laser

Indications for Use *(Describe)*

The Sterling Supreme Diode Laser is indicated for dentistry and oral soft tissue procedures of:
1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissues including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue;
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching 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.

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510(k) Summary

Prepared By: Robert K. Larsen
Preparation Date: September 21, 2017

Contact Information:

Contact Name:	Robert K. Larsen
Contact Title:	Regulatory Affairs Manager
Address:	4628 West Skyhawk Drive West Jordan, UT 84084
Contact Phone #:	801-256-9282
Contact Email:	rob.larsen@caogroup.com

Device Name:

Trade Name:	Sterling Supreme Diode Laser
Common Name:	Soft Tissue Diode Laser
Product Code 1:	GEX
Regulation 1:	878.4810
Product Classification 1:	Powered Laser Surgical Instrument Class II
Product Code 2:	ILY
Regulation 2:	890.5500
Product Classification 2:	Lamp, Infrared, Therapeutic Heating Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Precise SHP Diode Laser, manufactured by CAO Group, Inc. (K123443)

Rationale for Substantial Equivalence:
The submitted device and identified predicate device share exactly identical indications for use in dentistry and oral soft tissue procedures:

1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissues including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue;
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

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The submitted device and predicate device share similar design features including emission sources, operating controls, key constructional components, and materials of construction. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output, emission wavelength, and energy type.

Description of Submitted Device:

The Sterling Supreme Diode Laser is a device for delivering laser energy to human soft tissue for a variety of dental and oral 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 3 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber fully ensheathed within a coated steel coil terminated in a handpiece assembly, 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 cause hemostasis, ablation, or vaporization. The device features some user definable settings, including a selectable 650nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options. The device allows for selection of factory-established presets for common dental and oral care procedures, and allows for the operator to save desired settings for quick-reference.
Laser energy is transmitted through the fixed length of optical fiber to the distal end of the handpiece assembly. The handpiece assembly consists of a reusable, removable, sterilizable handpiece sleeve, and for surgical procedures is terminated with a single-use disposable tip. The operator uses the handpiece assembly 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 wireless foot-actuated switch.

Description of Predicate Device:

The Precise SHP Diode Laser is a device for delivering laser energy to human soft tissue for a variety of dental and oral 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 3 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber fully ensheathed within a coated steel coil terminated in a handpiece assembly, 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 cause hemostasis, ablation, or vaporization. The device features some user definable settings, including a selectable 650nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options. The device allows for selection of factory-established presets for common dental and oral care procedures, and allows for the operator to save desired settings for quick-reference.
Laser energy is transmitted through the fixed length of optical fiber to the distal end of the handpiece assembly. The handpiece assembly consists of a reusable, removable, sterilizable handpiece sleeve, and for surgical procedures is terminated with a single-use disposable tip. The operator uses the handpiece assembly 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 wireless foot-actuated switch.

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Indications for Use of the Submitted Device:

The Sterling Supreme Diode Laser is indicated for use for -

1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissues including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue;
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

Technological Characteristics and Substantial Equivalence:

	CAO Group, Inc. Sterling Supreme	**CAO Group, Inc. Precise SHP**
Working Beam Output Wavelength	810±10 nm	810±10 nm
Working Beam Output Power	0.1 - 3.0 watts	0.5 - 3.0 watts
Aiming Beam Output Power	< 3mW	< 3mW
Aiming Beam Output Wavelength	650±20 nm	650±20 nm
Laser Source	AlGaAs Diode	AlGaAs Diode
Laser Activation	Wireless foot pedal 2.40 - 2.48 GHz, IEEE 802.15.4 Protocol	Wireless foot pedal 2.40 - 2.48 GHz, IEEE 802.15.4 Protocol
Pulse Control	Digital emission control Fixed pulse duration of 0.05 seconds, 10Hz	Digital emission control Selectable fixed pulse duration of 0.03, 0.05, or 0.075 seconds, all at 10Hz
Cooling Method	Heatsink / Fan air cooled	Heatsink / Fan air cooled
Electrical Power Input (System)	100-240 VAC @ 47-63 Hz, 1.6A (switchable)	100-240 VAC @ 47-63 Hz, 1.6A (switchable)
User Interface	Color LCD Touch Screen	Color LCD Touch Screen
Laser Delivery System	Sheathed quartz optical fiber	Sheathed quartz optical fiber
Handpiece design	Inner stem composed of stainless steel permanently attached to the fiber cable; Removable, sterilizable anodized aluminum outer sleeve	Inner stem composed of stainless steel permanently attached to the fiber cable; Removable, sterilizable anodized aluminum outer sleeve
Patient Contact Articles	Single use disposable tip composed of silica quartz, stainless steel, and ABS plastic	Single use disposable tip composed of silica quartz, stainless steel, and ABS plastic

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	CAO Group, Inc. Sterling Supreme	CAO Group, Inc. Precise SHP
Energy emissions for select device presets		
Curettage	1.4 watts, Pulse, 30-second timer	1.4 watts, 0.05 Pulse
Gingivectomy	1.0 watts, continuous emission	1.0 watts, continuous emission
Phototherapy - Pain Relief	321 J/cm^2 (2.0 watts, continuous emission, therapy tip, 5 minute exposure)	321 J/cm^2 (2.0 watts, continuous emission, therapy tip, 5 minute exposure)
Whitening	900 J (3 watts, Continuous, 5 minute total exposure)	900 J (3 watts, Continuous, 5 minute total exposure)
Dimensions	7.5" x 5.5" x 4"	5.5" x 4.75" x 2.375"
Weight	3.5 lbs	4.0 lbs
510(k) Number	Pending this application	K123443
Indications for Use	The Sterling Supreme Diode Laser is indicated for dentistry and oral soft tissue procedures of: 1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissues including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue; 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions; 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.	The Pioneer Elite Diode Laser is indicated for dentistry and oral soft tissue procedures of: 1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissues including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue; 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions; 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

To summarize the technological characteristics, the submitted device and the predicate device share the same technology of generating 810nm infrared laser energy via solid state diodes. The submitted and predicate devices share the same methods of delivering the laser energy through a silica quartz fiber to an affixed handpiece assembly. The devices share the same method of using a single-use disposable tip composed of the same materials for delivering the laser energy to the treatment site. The devices share the same functionality of a wireless footswitch to activate the 810nm laser energy, such wireless footswitches using the same wireless frequency and transmission technology. The devices share the same method of digital pulse control, with similar manner of fixed pulse width. The devices share the same indications for use. The devices share similar usage of color touchscreen technology as the user interface.

The devices differ in the physical shape of the device. The devices differ in that the predicate uses an off-the-shelf component as the touchscreen interface, while the submitted device uses an embedded color touchscreen interface.

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Conformity to Standards:

The Sterling Supreme Diode Laser is designed to comply with the performance requirements of ANSI/AAMI ES60601-1:2005+A1 (Edition 3.0), AAMI/ANSI/ IEC 60601-1-2:2007 (Edition 3.0), IEC 60601-1-6:2013 (Edition 3.1), IEC 60601-2-22:2007 (Edition 3.1), and IEC 60825-1:2007 (Edition 2.0).

Performance Data:

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

- QAC-OP0298 - Final assembly inspection of Sterling Supreme Diode Laser
- Sterling Supreme Main and Safety Specification Verification Test

Results of these tests demonstrate the product meets the device's labeled specifications.

Conclusion:

The Sterling Supreme 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.