September 10, 2019

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

Re: K181602
Trade/Device Name: Pioneer Elite 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: June 8, 2018
Received: June 19, 2018

Dear Robert 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. 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,

Purva Pandya
Acting Assistant Director
Light Based Energy Devices Team
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181602

Device Name
Pioneer Elite Diode Laser

Indications for Use *(Describe)*
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 tissue 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 blood 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 K181602

Applicant Information:

Company Name: CAO Group, Inc.
Company Address: 4628 West Skyhawk Drive
West Jordan, Utah 84084 U.S.A.
Company Phone: 1-801-256-9282
Company Fax: 1-801-256-9287

Contact Person: Robert K. Larsen

Preparation Date: September 6, 2019

Device Name:

Trade Name:	Pioneer Elite Diode Laser
Common Name 1:	Soft Tissue Diode Laser
Product Code 1:	GEX
Regulation 1:	878.4810
Product Classification 1:	Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Pioneer Elite Diode Laser, manufactured by CAO Group, Inc. (K131059)

Description of Submitted Device:

The Pioneer Elite 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 3 watts of energy output. The laser energy is delivered to 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 device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is incorporated into the device. The activation of the working beam diodes is completed by use of a foot-actuated switch.

Indications for Use of the Submitted Device:

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 tissue 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 blood 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.

Rationale for Substantial Equivalence:

The submitted device is the exact same device as the predicate, excepting for labeling changes that are presented in this application. There is no change in the indications for use. There is no change in the materials of construction. There is no change in operating principle. A modification is presented in the submitted device wherein the single-use disposable applicator tips provided for the device shall not be delivered to the end-user in a sterile condition. The device instructions for use indicate suitable materials and method for the end-user to sterilize the tip prior to use. This change represents only a labeling change to the device, and the intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

Performance Data:

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

The Pioneer Elite Diode Laser is designed to comply with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated June 24, 2007. The device also complies with the recognized standards of IEC 60601-2-22 Edition 2 and IEC 60825-1 Edition 1. The device is designed in compliance to the entirety of IEC 60601-1: 2nd Edition, IEC 60601-1-2, and IEC 60601-1-4.

PERFORMANCE BENCH TESTING

No new risks or concerns regarding device performance are raised in modifying the device to provide the single-use tips to the market in a non-sterile state. No performance characteristics or specifications of the device are modified.

BIOCOMPATIBILITY

There are no modifications to the materials used in the device. Risk assessment activities demonstrate that presenting the single-use tips to the end-user in a non-sterile state does not introduce any increased risks or concerns so long as provided instructions for use are followed relative to processing the tips by the end-user prior to use.

END-USER STERILIZATION

Verification and validation testing indicate that treatment of the tips with an approved liquid chemical sterilant is capable of achieving a log 6 reduction in bioburden, without adversely impacting the performance or specifications of the tip. Verification tests show that rinsing the tips after treatment with the sterilant adequately removes residual sterilant from the tip.

Conclusion:

The modifications to the Pioneer Elite Diode Laser wherein the single-use tips are delivered to the end-user in a non-sterile condition do not present any new concerns over safety and effectiveness of the device. The modifications consist only of changes to the device labeling and instructions for use for the end-user to be aware of the present condition of the tips and to properly prepare the tips for use. All other aspects of the device, including indications for use, are not affected by this change.