

K 061366

510(k) Summary of Safety and Effectiveness

CAO Group, Inc.
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JUL 10 2006

Robert Larsen,
Preparation Date: May 8, 2006

Device Name:

Trade Name: DenLaser 800 Plus

Common Name: 810nm Diode Laser

Product Classification: Laser Instrument, Surgical

Legally Marketed Predicate Devices for Substantial Equivalence:

Odyssey 2.4G Diode Laser

DenLaser 800, Manufactured by CAO Group, Inc.

Cynosure Accolade Laser

Rationale for Substantial Equivalence:

The aforementioned laser devices and their accompanying delivery systems share similar indications for use in the oral environment, similar design features including wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output and energy type. The devices share similar applications to soft tissue.

Description of Submitted Device:

The DenLaser 800 Plus is a device for delivering laser energy to surfaces within the oral cavity. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at $810 \pm 20\text{nm}$ for a maximum of 5 watts of energy output. The laser energy is delivered to surgical site by means of a proprietary optical fiber system, which allow for the safe transmission of laser energy to the site without creating undue risk to the patient or operator 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 option.

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

Intended Uses of the DenLaser 800 Plus diode laser system:

The device is intended to be used for a variety of surgical procedures on soft tissue within the oral cavity. See Indications for Use on page 2-1.

Technological Characteristics and Substantial Equivalence:

The Odyssey 2.4G Diode Laser uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 630nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission. The device features a wireless foot switch for actuating the working beam. The maximum output of the working beam is 5 watts.

The DenLaser 800 uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 630nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission. The maximum output of the unit 5 watts.

The Cynosure Accolade Laser uses an excited Alexandrite crystal to generate a laser wavelength of 755nm. The system uses and optical fiber to deliver laser energy to the surgical site. The system also features a 635nm aiming beam. The system is used to apply laser energy to cutaneous and subcutaneous pigmentations, whether naturally occurring or artificially applied. The discolorations absorb the laser energy causing the discoloration to become altered such that the color is removed. The maximum output of the unit is 1.8J at a pulse width of 60 nanoseconds.

Performance Standards:

The DenLaser 800 Plus diode laser complies with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with IEC 60601-1:1998+A1, IEC 60601-2-22:1995, IEC 60825-1:1993+A1+A2, 47 CFR 15 and 18, and ETSI 301-489-1.

Clinical Performance Data

See Part 7: Performance Data

Conclusion

The DenLaser 800 Plus is substantially equivalent to the listed laser surgical devices without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2006

CAO Group, Inc.
% Mr. Robert Larsen
Operations Director
8683 South 700 West
Sandy, Utah 84070

Re: K061366

Trade/Device Name: DenLaser 800 Plus
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 8, 2006
Received: May 16, 2006

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set

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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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 061366

Device Name: DenLaser 800 Plus

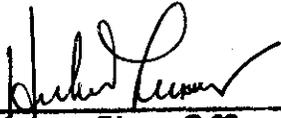
Indications For Use:

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
- Photocoagulation

Prescription Use AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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