510(k) Summary of Safety and Effectiveness

K062619

CAO Group, Inc.
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Robert Larsen,
Preparation Date: August 15, 2006

NOV 14 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, manufactured by Ivoclar Vivadent, Inc. (K050453)

Ceralas D 810 Diode Laser, manufactured by Biolitec, Inc. (K032864)

Aurora SL Diode Laser, manufactured by Premier Laser Systems, Inc. (K993285)

Rationale for Substantial Equivalence:

The aforementioned laser devices and their accompanying delivery systems share similar indications for use on soft tissue with the submitted device for cutting soft tissue, affecting lesions, and photocoagulation. The predicate devices and submitted device share 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 human soft tissue for a variety of surgical procedures. 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 surgical site by means of a proprietary 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 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. 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 Ceralas D 810 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 635nm 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 is 15 watts.

The Aurora SL 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 630-680nm aiming beam and features controls that allow for adjusting the output of the working beam. The maximum output of the unit is 6 watts.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CAO Group, Inc.
% Mr. Robert K. Larsen
Operations Director
4628 West Skyhawk Drive
West Jordan, Utah 84084

NOV 14 2006

Re: K062619
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: August 15, 2006
Received: September 6, 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

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): K062619

Device Name: *DenLaser 800 Plus*

Indications For Use:

The DenLaser 800 Plus is indicated for the procedures of

> removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation

on soft tissue in the fields of

> otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, plastic surgery, urology, gynecology, and plastic surgery.

Prescription Use X **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

510(k) Number K062619