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optoelectronics laser applications light emitting diodes

September 19, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852 USA

Re: Application for Variance
Accession Number: 0210362

Director, CRDH,

This is to inform you of the intent of CAO Group Inc. to request a variance for the DenLaser 800 soft tissue surgery device. The scope of the request involves the requirement of a beam attenuator as indicated in 21 CFR Part 1040.10(f)(6)(i). The request for variance is discussed at length in the document herein.

Please contact myself or Densen Cao at the following numbers for any questions or additional information: Ph: 801.256.9282 or Fax: 801.256.9287.

Best Regards,

Robert Larsen
Operations Manager

2003V-0454

VAR1

Application for Variance

CAO Group Inc.
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Preparation Date: September 19, 2003

Application for Variance for CAO Group's DenLaser 800 soft tissue surgery device

Accession Number: 0210362

Product Type [per 21 CFR, Part 1002.1]:

Class IV Optical Laser Product

Trade Name:	DenLaser 800, Odyssey Diode Laser
Common Name:	Diode Laser 810 nm
Classification Name:	Laser Instrument, Surgical
Model:	DenLaser 800, Odyssey Diode Laser

Product Description

This product is a solid-state laser device, emitting laser radiation at a wavelength of 810 ± 20 nm and a power output of no greater than 5 watts. Laser radiation is generated by solid-state semiconductor diodes within a sealed aluminum housing. The laser radiation is then collected within the sealed housing to a fiber optic port in the housing wall. A shielded optical fiber is then secured to the sealed housing wall, and the laser radiation is conducted within the fiber through the unit exterior housing. The fiber end is positioned within a few millimeters of the surgical site, at which point the laser radiation emits from the fiber end and strikes the surgical site. The optical fiber is in two segments: 1) a shielded optical fiber that conducts the laser radiation from the sealed emitter module to the unit exterior housing and, 2) an optical fiber that conducts the laser radiation from the external housing to the surgical site. At all points where the laser light is exchanged from one part to the next – from the emitter module to the internal fiber, and from the internal fiber to the external fiber – the interface is secured by metal connection jacks, ensuring that the air gap between components is no greater than 50μm, which air gap is fully contained within the connector. The connection between the external and

internal fibers may be uncoupled during maintenance, but device instructions indicate the device is to be disconnected from the power supply at any time when this connector is uncoupled. With this connection point open, a mechanical attenuator in the form of a gravity closed cover does exist to prevent laser emission should unit activation be conducted contrary to instructions. This attenuator cannot function when the unit is properly assembled. The laser is compliant with all requirements of this Part, except that for which the variance is requested. To energize the laser emitter module, a main power switch, key switch, initialization switch, any remote interlock that is attached to the device, and a momentary foot activation switch must all be activated. Deactivation of any one of these or the housing interlock, or activation of the emergency stop switch will discontinue electrical power to the emitter module.

Indications for Use

This device is indicated for:

Dental, Oral, and Soft Tissue Surgery including:
- Sulcular Debridement of Diseased or Fibrous Tissue
- Excision and Biopsy
- Gingivectomy and Gingivoplasty
- Lesion and Fibroma Removal
- Tissue Retraction
- Bacterial Decontamination
- Aphthous Ulcers
- Gingival Hyperplasia
- Crown Lengthening
- Operculectomy
- Frenectomy
- Photocoagulation

Explanation of Request

A variance is requested for 21 CFR Part 1040.10(f)(6)(i), which indicates the requirement of a beam attenuator for all Class II, III, and IV laser products. Although not defined in 21 CFR 1040, the Compliance Guide for Laser Products (HHS Publication FDA 86-8260) defines a beam attenuator as a mechanical or electrical device which blocks laser emission. It is requested that the requirement for a beam attenuator not be applicable to the external fiber portion of this device.

Advantages for the Variation

As indicated in the device description above, the laser radiation is wholly contained from the point of emission to the intended point of delivery. This design promotes the efficiency of the device, requiring less output power at the emitter module to deliver a given output at the delivery end compared to other laser devices. The complete encasement of the laser energy from the emission point to the intended point of

delivery is designed to greatly reduce access to laser radiation at any point other than the delivery point. The implementation of a beam attenuator in the device would require a substantial gap along the beam path within the unit, decreasing transmission efficiency and increasing the potential for secondary or scattered laser emissions within the housing.

Alternate or Suitable Protection

The use of continuous shielding and optical fiber as described above virtually eliminates the possibility of scattered or secondary radiation from any point of the device other than the intended delivery point. The use of a momentary actuation switch to deliver electrical power to the emitter module, in addition to any one of three readily accessible control switches, are capable of deactivating the emitter module and terminating laser emissions. It is our position that preventing the emission of laser energy is as good, if not preferable, to the blocking or redirecting of an existent energy beam. We feel that the introduction of an attenuator device would increase the overall access to secondary or scattered laser energy, and that a risk of exposure to unintended or accidental radiation is increased compared to our current design. These containment and control methods as here identified constitute our proposal for an alternative to the beam attenuator that is required.

Application of the Variance

This variance is requested for devices listed in Appendix A: Brand Name Manufacturer List. It is requested that the variance be applicable to the manufacture of the device as it is defined herein and in the Product Report under this Accession Number for an undefined period of time. The variance will not apply to any redesign that affects the safety and compliance measures for this device as it is on record with the CDRH, nor will it apply to any device not listed in Appendix A unless such Appendix is amended, along with a description of the differences between devices listed herein and those of the amended document. This variance will apply to a total not to exceed 2000 units manufactured per year for all models listed. The Office of the Director will be notified if manufacture of this device will exceed this rate of production.

Appendix A
Brand Name Manufacturer List
In accordance with 21 CFR, Part 1010.3(c)

Brand Name: DenLaser 800

Manufactured For:
CAO Group, Inc.
8683 South 700 West
Sandy, UT 8407
801-256-9282

Brand Name: Odyssey Diode Laser

Manufactured For:
Ivoclar Vivadent, Inc.
175 Pineview Dr.
Amherst, NY 14228
1-800-533-6825