K962948

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510(k) Summary

For CeramOptec, Inc.'s

Ceralas G Frequency Doubled Nd:YAG Laser

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

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as Regulatory Counsel to CeramOptec, Inc.

Contact Person:

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Date Prepared:

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Name of Device and Name/Address of Sponsor:

Ceralas G Frequency Doubled Nd:YAG Laser System and accessories

CeramOptec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name:

Ophthalmic laser

Predicate Devices:

1. Biovision Crystal Emerald Focus
2. Zeiss Diode Pumped Solid State Laser
3. Coherent Innova Argon and Coherent Series 599 Dye Laser
4. HGM Compac 110 Argon Laser

Intended Use

The Ceralas G is intended to be used as a surgical instrument for photocoagulation of ocular tissue as well as ablation of tissue of the iris and trabeculum. It is already cleared for photocoagulation of retinal tissue.

Technical Characteristics and Substantial Equivalence

The Ceralas G is a complete self-contained compact surgical laser that utilizes a neodymium-doped yttrium aluminum garnet ("Nd:YAG") crystal. The Ceralas G has already been cleared by FDA (K954834) for use as a surgical instrument for photocoagulation of retinal tissue using a hand held fiber optic delivery system. The purpose of this submission is to extend the indications for use of the cleared laser to include photocoagulation of ocular tissue and ablation of tissue of the iris and trabeculum. As explained in this 510(k) notice, the Ceralas G can be attached using an adaptor provided by the Company, without hardware modification, to the Carl Zeiss (K874160 and K925641) or Haag-Streit (K792083) slit lamps, and to the Keeler indirect ophthalmoscopes (K854244 and K942104). No hardware changes have been made to the originally cleared Ceralas G laser. Only certain minor software modifications are required to use the slit lamp as a delivery system. Use of the Ceralas G laser with slit lamps and indirect ophthalmoscopes permits photocoagulation of ocular tissue and ablation of tissue of the iris and trabeculum with the Ceralas G laser. The CeramOptec fiber optic laser delivery system intended for use with the Ceralas G Nd:YAG Laser System has already received clearance from FDA (K935747).

The Ceralas G and the predicates have the same indications for use; photocoagulation of ocular tissue (Biovision Laser, Zeiss Laser, and Coherent Laser) as well as ablation of tissue of the iris and trabeculum (HGM Laser). The lasers are all intended to be used with slit lamps, indirect ophthalmoscopes, and endocular probes. The Ceralas G was cleared for photocoagulation of retinal tissue. This submission expands the intended use of the Ceralas G to use with slit lamps and indirect ophthalmoscopes.

The lasers also have very similar treatment beam wavelengths and powers, and can operate in both continuous and pulsed exposure modes. The wavelength of the treatment beam for the Ceralas G, the Biovision Laser, and the Zeiss Laser is 532 nm, and the wavelength of the Coherent Laser is in a range consisting of 488 - 514 nm and 577 - 630 nm. They also have very similar treatment beam power outputs. The Ceralas G and the Biovision Laser both can provide a treatment beam of 0.1 - 3 Watts ("W"). The Zeiss Laser can provide a treatment beam of 0.1 - 1 W and the Coherent Laser can provide a treatment beam of 0.1 - 4 W (Argon) and 0.05 W - 170 W (Dye). The Ceralas G has a pulsed mode exposure duration of 0.1 - 1 sec; the Biovision Laser, 0.01 - 3 sec; the Zeiss Laser, 0.01 - 0.5 sec; and the Coherent Laser, 0.01 - 5 sec. The differences in pulsed mode

exposure duration between the Ceralas G and the predicates do not raise new issues of safety or effectiveness because the range of exposure durations is very similar between the Ceralas G and the predicate lasers.

The Ceralas G and the HGM Laser both have very similar treatment beam wavelengths and powers, and can operate in both continuous and pulsed exposure modes. The wavelength of the Ceralas G's treatment beam is at 532 nm and the HGM Laser's treatment beam is distributed in a range between 488 - 529 nm with the largest line at 514 nm. The difference in wavelength between the Ceralas G and the HGM Laser does not raise any new issues of safety or effectiveness because the wavelength range for the HGM Laser includes a wavelength within 3 nm of the wavelength emitted by the Ceralas G.

Both lasers also have very similar treatment beam power outputs. The Ceralas G's treatment beam power output is 0.1 - 3 W and the HGM Laser's treatment beam power output is 0.1 - 1 W. The Ceralas G has a pulsed mode exposure duration of 0.1 - 1 sec and the HGM Laser has a pulsed mode exposure duration of 0.01 - 0.5 sec. Although the Ceralas G can achieve power outputs up to 3 W and use a 1 sec exposure duration, the User's Manual instructs the physician to start a procedure using only 0.1 W of power and an exposure duration of 0.1 - 0.2 seconds. The physician is instructed to then gradually increase the power or exposure duration to achieve the desired tissue effect. Thus, the difference in maximum power output and exposure duration does not raise new issues of safety or effectiveness because the physician is instructed to use a power only as high and an exposure duration only as long as necessary to achieve the desired tissue effect.

The minor differences in the wavelength and power of the treatment beams do not raise any new issues of safety or effectiveness because: (1) the Ceralas G and the predicate lasers all can be operated with a slit lamp, an indirect ophthalmoscope and a fiber optic delivery system; (2) the Ceralas G and the Biovision Laser are indicated for photocoagulation of ocular tissue, have a very similar pulsed mode exposure duration, and have a treatment beam which operates at 532 nm with 0.1 - 3 W of power; (3) the Ceralas G and the HGM Laser, both of which are indicated for ablation of tissue of the iris and trabeculum, have very similar treatment beam wavelengths; and (4) while there are minor differences in the power and pulsed mode exposure duration of the treatment beam between the Ceralas G and the HGM Laser, the Ceralas G's User's Manual instructs the physician to start with a low power and exposure duration and increase to achieve the desired tissue effects. Any other minor differences between the Ceralas G and the predicate devices, such as the systems' dimensions and weight, do not raise new questions of safety and effectiveness.