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**510(k) SUMMARY
FOR CERAMOPTEC INC.'S
CERALAS DIODE LASER SYSTEM (MODEL D2)**

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

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as Regulatory Counsel to CeramOptec, Inc.

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Name of Device and Name/Address of Sponsor

Ceralas Diode Laser System (Model D2)

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

Classification Name

Ophthalmic laser

Common or Usual Name

Diode Laser

Proprietary Name

Ceralas Diode Laser System (includes the Ceralas D2 laser and accessories)
("Ceralas D2")

Predicate Devices

- (1) Iris Medical Oculight SLx
- (2) Keeler Microlase SL
- (3) Nidek DC3000

Intended Use

The Ceralas D2 and the predicates have the same intended use; photocoagulation of ocular tissue. The Oculight SLx is intended to be used to perform retinal photocoagulation as well as anterior segment procedures.

The Keeler Microlase SL is intended for use in ophthalmic photocoagulation and is specifically indicated for use in the treatment of glaucoma and all retinal vascular diseases. The Nidek DC3000 is promoted as an ophthalmic photocoagulator. The Ceralas D2 and its predicates are all intended for the photocoagulation of ocular tissue which includes the retina as well as the anterior segment.

Technological Characteristics and Substantial Equivalence

The Ceralas D2 is a complete self-contained compact surgical laser that utilizes gallium aluminum arsenide ("GaAlAs") semiconductor diodes to generate near-infrared laser radiation. The laser employs a modular design comprised of: (1) a laser diode and cooling module containing the laser diode; (2) an optics module containing a beamsplitter pickoff for automatic control of total optical power; (3) front control and display panels; and (4) RFI-shielded, transformer isolated power supplies and control electronics. A fiber optic delivery system is coupled to the laser via an SMA-905 connector to deliver laser radiation to the target tissues. The fiber optic delivery system available with the Ceralas D2 consists of fibers with 200 um diameters.

The Ceralas D2 is substantially equivalent to the predicate devices because they have the same intended use, principles of operation and technological characteristics. The Ceralas D2, like the predicate devices, is a microprocessor controlled, solid state laser that can be operated with slit lamps, indirect ophthalmoscopes, and endocular probes. The lasers all use diodes to create a laser treatment beam. The Ceralas D2 emits a beam between 780 and 840 nm, nominally at 810 nm; the Keeler Microlase SL emits light between 780 and 840 nm; and the Oculight SLx emits light nominally around 810 nm. The Ceralas D2, the Oculight SLx, and the Nidek DC3000 all have maximum laser treatment beam powers of 2 watts.

The laser treatment beam emitted by the Ceralas D2 and the predicates can be delivered continuously or in pulses. The Ceralas D2's pulse can be varied from 0.1 to 99.9 seconds, *i.e.*, to an effectively continuous delivery mode. The Oculight SLx has pulses of up to a 9 second duration. The pulse duration for the Keeler Microlase SL ranges between 0.01 and 1 second. Although there are differences between the pulse duration of the Ceralas D2 and the predicates, this difference does not raise any new issues of safety or effectiveness because the predicate lasers operate in both continuous and pulsed delivery modes and the Ceralas D2 merely provides pulse durations incrementing from 0.1 seconds to what is effectively a continuous delivery mode.