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K960971

**510(k) Summary  
IRIS Medical Instruments, Inc.  
OcuLight GL**

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

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Date Prepared: March 7, 1996

**Name of Device and Name/Address of Sponsor**

OcuLight GL

IRIS Medical Instruments, Inc.  
340 Pioneer Way  
Mountain View, CA 94041

**Classification Name**

Ophthalmic Laser Photocoagulator  
CFR Section: 886.4390  
Product Code: 86 HQF

**Predicate Devices**

The OcuLight GL Laser Photocoagulator system is substantially equivalent to other currently legally marketed laser photocoagulator devices including IRIS Medical OcuLight SL Laser Photocoagulator System (K894841), the Coherent Novus 2000<sup>®</sup> Laser Photocoagulator system (K913127); the Alcon Ophthalas<sup>®</sup> 532 Laser Photocoagulator System (K932062).

### **Intended Use**

The intended use of this device is retinal photocoagulation and laser trabeculoplasty to be performed by the ophthalmologist.

### **Technological Characteristics and Substantial Equivalence**

The OcuLight GL is a semiconductor-based laser photocoagulator console which delivers true continuous wave green laser light. The OcuLight GL uses infrared (808 nm) semiconductor diode laser light as the primary source of energy which is then wavelength converted to a visible green (532 nm) laser light for delivery to the patient's eye and treatment. A second visible red (630-650 nm) semiconductor CW laser is used for aiming.

The OcuLight GL is substantially equivalent to other currently legally marketed laser photocoagulator devices including the Coherent Novus 2000® Laser Photocoagulator system (K913127); the Alcon Ophthalas® 532 Laser Photocoagulator System (K932062); as well as the IRIS Medical OcuLight SL Laser Photocoagulator System (K894841). All of these predicate devices are indicated for retinal photocoagulation using slit lamp delivery, endophotocoagulation probes, and the laser indirect ophthalmoscope; and for laser trabeculoplasty using slit lamp delivery. The Coherent Novus 2000 uses an argon gas laser as the treatment laser. The colors of the treatment beam are blue (488 nm) and green (514 nm). A moving filter is used to restrict delivery of only green laser light when desired. Power delivered is true continuous wave. The color of the treatment beam for the Alcon Ophthalas 532 is green (532 nm). This beam is generated from a frequency-doubled Nd:YAG laser which is optically pumped by arc lamps and acousto-optically Q-switched. Power delivered is pulsed. The color of the treatment beam for the IRIS Medical OcuLight SL is infrared (810 nm). This beam is generated directly from a semiconductor laser diode. Power delivered is true continuous wave.

### **Device Description**

The OcuLight GL is a semiconductor-based ophthalmic laser photocoagulator which delivers true continuous wave green laser light. It will only be used in conjunction with three fiber optically coupled delivery devices which have received prior FDA-premarket clearance: the IRIS Slit Lamp Adapter (K912918 for retinal photocoagulation and K913430 for laser trabeculoplasty), the IRIS EndoProbe (K894841), and the IRIS Laser Indirect Ophthalmoscope (K903288).