

K 982031

SEP 8 1998

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

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

Daniel Marinsik  
IRIS Medical Instruments, Inc.  
1212 Terra Bella Avenue  
Mountain View, CA 94043-1824  
(650) 962-8100

Contact Person: (same as above)

Date Prepared: May 30, 1998

**FDA Establishment Registration Number**

2939653 For IRIDEX Corporation (Parent company of IRIS Medical  
& IRIDERM)

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

OcuLight GL with Dermatology Handpiece

IRIS Medical Instruments, Inc.  
1212 Terra Bella Avenue  
Mountain View, CA 94043-1824

**Classification Name**

Ophthalmic Laser Photocoagulator  
CFR Section: 886.4390  
Product code: 86 HQF  
510(k) K960971

Dermatology Laser System  
CFR Section: 878.4810  
Product code: 79 GEX  
(Additional Indications)

## **Predicate Devices**

The OcuLight GL Laser System with the Dermatology Handpiece is substantially equivalent to other legally marketed laser systems including and the IRIDERM DioLite 532 Laser System (K964074), the Continuum Biomedical, Inc., CB Diode/532 Laser System (K954905), the Laserscope, Aura Laser System (K951034), and the HGM Surgica™ K1 Multi-Color Laser System (K913569).

## **Intended Use**

The OcuLight GL is currently cleared for retinal photocoagulation and laser trabeculoplasty using ophthalmic delivery devices (IRIS Slit Lamp Adapter, IRIS Laser Indirect Ophthalmoscope, IRIS EndoProbe). The Dermatology Handpiece will expand the intended use of this device for the treatment of vascular and pigmented skin lesions.

## **Device Description**

The OcuLight GL is a semiconductor-based dermatology laser system which delivers true continuous wave green laser light. For the additional indication in the treatment of vascular and pigmented lesions it will be used in conjunction with fiber optically coupled Dermatology Handpieces which have received prior FDA-premarket clearance (K964074).

The OcuLight GL is a semiconductor-based laser console which delivers green laser light. The OcuLight GL uses infrared (808 nm) semiconductor diode laser light as the primary source of optical energy which is then wavelength converted to a visible green (532 nm) laser light for the treatment delivery.

A second visible red (630 –650 nm) semiconductor CW laser is used for aiming. The 532 nm treatment and 630-650 nm pilot/aiming beams are optically combined inside the laser head and therefore follow the same path. The treatment and aiming beams are coaxial (i.e. follow the same path) in the OcuLight GL. The aiming beam is turned on when the OcuLight is placed into Treat mode.

The delivery devices currently cleared for use with the OcuLight GL are the IRIS Slit Lamp Adapter (SLA), the IRIS EndoProbe, and the IRIS Laser Indirect Ophthalmoscope (LIO). Delivery devices not specifically intended for use with the OcuLight GL will not be recognized by the fiber interlock circuit as a valid delivery device.

For the new indications, the OcuLight GL will utilize the Dermatology Handpieces connected to the fiber port. As was true with the three previously FDA-cleared fiber optically coupled delivery devices used with the OcuLight GL, the distal end of the Dermatology Handpieces will be the laser aperture and not the fiber port on the laser console. The laser port is electronically interlocked so that no laser energy can be emitted without the correct connection of a recognized delivery device.

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

The OcuLight GL is a semiconductor-based laser 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 treatment delivery. A second visible red (630-650 nm) semiconductor CW laser is used for aiming.

The OcuLight GL with Dermatology Handpieces for the treatment of vascular and pigmented skin lesions is substantially equivalent to several other currently legally marketed laser systems including the IRIDERM DioLite 532; the Continuum Biomedical CB Diode/532; the Laserscope Aura and the HGM Surgica K1. All of these predicate devices are indicated for the treatment of vascular and pigmented skin lesions.

The DioLite 532 Laser System, Continuum Biomedical, Inc., CB Diode/532 Laser System, and the Laserscope, Aura Laser System, deliver the same wavelength as the OcuLight GL. The HGM Surgica™ K1 Multi-Color Laser System is indicated for ophthalmology and for dermatology and uses a shorter and longer wavelength. The OcuLight GL delivers similar power, has similar delivery devices, and performs similar indications as these predicate dermatology laser systems. Therefore, the OcuLight GL is substantially equivalent to these predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 8 1998

Mr. Daniel Marinsik  
Director Regulatory Affairs  
IRIS Medical Instruments, Inc.  
1212 Terra Bella Avenue  
Mountain View, California 94043

Re: K982031  
Trade Name: Oculight GL with Dermatology Handpiece  
Regulatory Class: II  
Product Code: GEX  
Dated: May 30, 1998  
Received: June 10, 1998

Dear Mr. Marinsik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

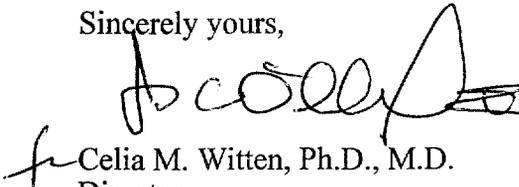
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Daniel Marinsik

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K 982031

Device Name: OcuLight GL with Dermatology Handpieces

Indications For Use:

The treatment of vascular and pigmented skin lesions.

(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 Devices

510(k) Number

K982031

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_