K050562

APR 1 4 2005

510(k) Summary
IRIDEX Corporation
IRIS Medical® OcuLight® GL/GLx

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

John Jossy
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043
(650) 962-8848 ext. 3016

Contact Person: (same as above)

Date Prepared: May 23, 2003

Name of Device and Name/Address of Sponsor

IRIS Medical OcuLight GL/GLx Laser Systems

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Classification Name

Laser Instrument, Surgical, Powered
CFR Section: 878.4810 and 886.4390
Product Code: GEX and HQF

Predicate Devices

The OcuLight GL/GLx laser systems are substantially equivalent to other currently legally marketed ophthalmology laser devices including ~~OcuLight SL/SLx laser~~ systems and the Lumenis Novus Spectra (K022327).

Device Description

The OcuLight GL/GLx is a semiconductor-based laser that delivers true continuous wave green laser (532 nm) light for the indication of retinal photocoagulation, laser trabeculoplasty, the treatment of vascular and pigmented skin lesions, and other laser treatments. Visible red (630-650 nm) semiconductor diode laser is used for aiming.

K050562

Intended Use

The OcuLight GL/GLx is indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty, the treatment of vascular and pigmented skin lesions, stapedotomy, stapedectomy, and other ear, nose, and throat (ENT) applications. The following are examples of applications for the OcuLight GL/GLx laser systems.

Condition	**Treatment**
Diabetic Retinopathy • Nonproliferative Retinopathy • Macular Edema • Proliferative Retinopathy	Retinal Photocoagulation (RPC); Focal and Grid Laser Treatments
Glaucoma • Primary Open Angle • Closed Angle • Refractory Glaucoma	Laser Trabeculoplasty; Iridotomy; Iridoplasty
Retinal Tears and Detachments	RPC; Focal and Grid Laser Treatments
Lattice Degeneration	RPC; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD)	RPC; Focal and Grid Laser Treatments
Intra-Ocular Tumors • Choroidal Hemangioma • Choroidal Melanoma • Retinoblastoma	RPC; Focal and Grid Laser Treatments
Retinopathy of Prematurity	RPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	RPC; Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	RPC; Focal and Grid Laser Treatments
Dermatology • Pigmented Skin Lesions • Vascular lesions	Focal Laser Treatments
Ear, Nose and Throat • Otosclerotic hearing loss and/or diseases of the inner ear	Stapedectomy Stapedotomy Myringotomies Lysis of Adhesions Control of Bleeding Removal of Acoustic Neuromas Soft tissue Adhesion in Micro/Macro Otologic Procedures

K050562

Technological Characteristics and Substantial Equivalence

The OcuLight GL/GLx is indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty, the treatment of vascular and pigmented skin lesions, stapedotomy, stapedectomy, and other ENT applications. The expansion of the indications for use for the proposed OcuLight does not result in a change to the hardware or firmware for the currently marketed OcuLight GL/GLx.

The OcuLight SL/SLx Laser Systems are indicated for Retinal Photocoagulation, Laser Trabeculoplasty, Transscleral Cyclophotocoagulation (TSCPC), Transscleral Retinal Photocoagulation (TSRPC), Iridotomy, and Iridoplasty. The OcuLight SL/SLx diode laser systems feature a combination of pulsed diode laser and optical fiber technology to deliver the correct balance of 810 nm wavelength, spot size, and pulse duration for effective laser photocoagulation.

The Lumenis Novus Spectra Diode Laser System is indicated for many Ophthalmic, Ears, Nose and Throat (including stapedectomy), Dermatological and Dentistry applications. The Lumenis Novus Spectra delivers the same 532nm wavelength, pulses of equivalent duration, treatment spots of equivalent size, and energy densities equivalent to the OcuLight GL/GLx.

Non-Clinical performance Data

None

Clinical performance Data

None

Conclusion

The OcuLight GL/GLx is substantially equivalent to the predicate devices currently legally marketed for stapedotomy, stapedectomy, and other ENT applications as shown in the Indications for Use statement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2005

IRIDEX Corporation
c/o John Jossy
Director of Regulatory Affairs and Quality Assurance
1212 Terra Bella Avenue
Mountain View, CA 04043

Re: K050562
Trade/Device Name: IRIS Medical OcuLight GL/GLx Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 4, 2005
Received: March 8, 2005

Dear Mr. Jossy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K050562

Device Name: IRIS Medical® OcuLight® GL/GLx

Indications For Use:

The IRIDEX OcuLight GL/GLx is used in ophthalmic, dermatology, and ear nose and throat (ENT) applications. Specific indications are listed below:

Condition	**Treatment**
Diabetic Retinopathy • Nonproliferative Retinopathy • Macular Edema • Proliferative Retinopathy	Retinal Photocoagulation (RPC); Focal and Grid Laser Treatments
Glaucoma • Primary Open Angle • Closed Angle	Laser Trabeculoplasty; Iridotomy, Iridoplasty
Retinal Tears and Detachments	RPC; Focal and Grid Laser Treatments

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K050562

Device Name: IRIS Medical® OcuLight® GL/GLx

Indications For Use:

Condition	Treatment
Lattice Degeneration	RPC; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD)	RPC; Focal and Grid Laser Treatments
Intra-Ocular Tumors • Choroidal Hemangioma • Choroidal Melanoma • Retinoblastoma	RPC; Focal and Grid Laser Treatments
Retinopathy of Prematurity	RPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	RPC; Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	RPC; Focal and Grid Laser Treatments

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K050562

Device Name: IRIS Medical® OcuLight® GL/GLx

Indications For Use:

Condition	Treatment
Dermatology • Pigmented Skin Lesions • Vascular lesions	Focal Laser Treatments
Ear, Nose and Throat • Otosclerotic hearing loss and/or diseases of the inner ear	Stapedectomy Stapedotomy Myringotomies Lysis of Adhesions Control of Bleeding Removal of Acoustic Neuromas Soft tissue Adhesion in Micro/Macro Otologic Procedures

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050562