DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Mr. John Jossy
Director, Regulatory Affairs and Quality Assurance
Iridex Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824

Re: K040209
Trade/Device Name: IRIS Medical® IQ 810 Diode Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF, GEX
Dated: August 23,2004
Received: August 25,2004

Dear Mr. Jossy:

This letter corrects our substantially equivalent letter of September 20,2004.

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 (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.

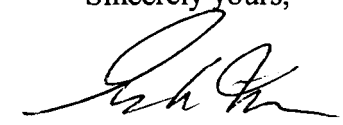
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-0115. 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/dsma/dsmamain.html

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K 040209

Device Name: IRIS Medical® IQ 810 Laser Photocoanulator

Indications For Use:

The WDEX IQ 810 is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other laser diode treatments. The following are examples of applications for the IQ 810.

Condition	Treatment
Diabetic Retinopathy • Nonproliferative Retinopathy • Macular Edema • Proliferative Retinopathy	Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments
Glaucoma • Primary Open Angle • Closed Angle • Refractory Glaucoma (recalcitrant/uncontrolled)	Laser Trabeculoplasty; Iridotomy, Transscleral Cyclophotocoagulation (TSCPC)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040209

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K040209

Device Name: : IRIS Medical® IQ 810 Laser Photocoagulator

Indications For Use:

Condition	Treatment
Retinal Tears, Detachments, and Holes	Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments
Lattice Degeneration	PRP; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD) with Choroidal Neovascularization (CNV)	Focal and Grid Laser Treatments
Intra-Ocular Tumors • Choroidal Hemangioma • Choroidal Melanoma • Retinoblastoma	Focal and Grid Laser Treatments
Retinopathy of Prematurity	PRP; TSRPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	PRP; 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use X OR Over-The-Counter Use _____

510(k) Number K040209
(Per 21 CFR 801.109)

SEP 2 0 2004

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510(k) Summary
IRIDEX Corporation
IRIS Medical® IQ 810

K040209

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: November 3, 2003

Name of Device and Name/Address of Sponsor

IRIS Medical® IQ 810 Laser Photocoagulator

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Classification Name

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

Predicate Devices

The IQ 810 laser system is substantially equivalent to other currently legally marketed ophthalmology laser devices including IRIDEX Corporation's IRIS Medical OcuLight SLx Laser Photocoagulator (K020374).

Device Description

The IQ 810 is a semiconductor diode laser system that delivers infrared 810 nm laser light intended to be used for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy. Visible red (630-650 nm) semiconductor diode laser is used for aiming.

Intended Use

The IQ 810 is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other laser diode treatments. The following are examples of applications for the IQ 810 laser systems.

Condition	Treatment
Diabetic Retinopathy • Nonproliferative Retinopathy • Macular Edema • Proliferative Retinopathy	Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments
Glaucoma • Primary Open Angle • Closed Angle • Refractory Glaucoma (recalcitrant/uncontrolled)	Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC)
Retinal Tears, Detachments, and Holes	Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments
Lattice Degeneration	PRP; Focal and Grid Laser Treatments
Age-related Macular Degeneration (AMD) with Choroidal Neovascularization (CNV)	Focal and Grid Laser Treatments
Intra-Ocular Tumors • Choroidal Hemangioma • Choroidal Melanoma • Retinoblastoma	Focal and Grid Laser Treatments
Retinopathy of Prematurity	PRP; TSRPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	PRP; Focal and Grid Laser Treatments

Technological Characteristics and Substantial Equivalence

The IQ 810 has substantial hardware and software differences from currently marketed laser systems. However, a detailed comparison of the key characteristics between the SLx and the IQ 810 shows that the technology of the IQ 810 does not differ significantly from the predicate device (see Section VII-A-11 of 510k Notification).

The OcuLight SLx Laser System is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy.

The OcuLight SLx Laser System delivers similar power, has similar indications, and uses similar delivery devices to that of the IQ 810.

Non-Clinical performance Data

None

Clinical performance Data

None

Conclusion

The IQ 810 is substantially equivalent to predicate devices currently legally marketed for the indication of retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and iridotomy.