

Section 1- 510(k) Summary Statement

K071687

AUG - 7 2008

I. General Information

Submitter: IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043-1824

Contact Person: David Buzawa
Director of Regulatory Affairs and Quality Assurance

Summary Preparation Date: June 5, 2008

II. Names

Device Names: Family of IRIDEX IQ Laser Systems (IQ532, IQ577, IQ630-670, IQ810) & Delivery Device Accessories

Primary Classification Names: Laser Powered Surgical Instruments (and Accessories)

III. Predicate Devices

- IRIS Medical OcuLight TX
- IRIS Medical IQ 810 Diode Laser
- IRIS Medical OcuLight GL/GLx
- Asclepion Meditec AG Laser System Yellow Star
- Lumenis Novus Varia Ophthalmic Laser
- IRIDEX OtoProbe
- IRIDEX D'Amico\Peyman Fluted EndoProbe
- Straight and Illuminating LaserProbes – Adjustable Intuitive
- IRIDEX IRIS Medical G-Probe Handpieces
- IRIDEX IRIS Medical DioPexy Probe Handpieces
- IRIDEX Wireless Footswitch

IV. Product Description

The Family of IRIDEX IQ Laser Systems is comprised of the following main components:

- Main console containing the major electrical components, including:
 - Control Panel including control knobs (power, interval, duration or software assigned function), treat/standby button, and display;
 - Two delivery device fiber-optic connector ports (only one active at a time);
 - LIO illumination connection;
 - Smart key port for detecting/operating safety filters and/or accessory identification;
 - Emergency stop switch;
 - Key switch;
 - Connector ports for the footswitch, remote control, and power cord;

– **510(k) Summary Statement (continued)**

- A treatment Footswitch (either wired, wireless, or wireless with PowerAdjust);
- A Wired Remote Control that duplicates the control panel;
- Delivery Accessories including OtoProbe handpieces, EndoProbe handpieces, G-Probe and DioPexy Probe Handpieces, Dermatology Handpieces, Microscope Adapters, and Laser Indirect Ophthalmoscopes.
- Optional Cart/Stand

V. Indications for Use

The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]) and the hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse™, or LongPulse™ mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of , dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

532 nm

Dermatology

- Pigmented Skin Lesions
- Vascular Lesions

Ear, Nose, and Throat (ENT)/ Otolaryngology

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

Ophthalmology

Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty including:

- Retinal photocoagulation (RPC) for the treatment of
 - Diabetic retinopathy, including:
 - Nonproliferative retinopathy
 - Macular edema
 - Proliferative retinopathy
 - Retinal tears and detachments

– **510(k) Summary Statement (continued)**

- Lattice degeneration
- Age-related macular degeneration (AMD)
- Retinopathy of prematurity
- Sub-retinal (choroidal) neovascularization
- Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
 - Primary open angle/Closed angle

577nm

Dermatology:

- Treatment of Vascular and pigmented lesions

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids including :
 - proliferative and nonproliferative diabetic retinopathy;
 - choroidal neovascularization;
 - branch retinal vein occlusion;
 - age-related macular degeneration
 - retinal tears and detachments
 - retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle Glaucoma

630 – 670nm

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
 - proliferative and nonproliferative diabetic retinopathy;
 - choroidal neovascularization;
 - branch retinal vein occlusion;
 - age-related macular degeneration
 - retinal tears and detachments
 - retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

– **510(k) Summary Statement (continued)**

810nm

Ophthalmology:

Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following:

- Retinal photocoagulation for the treatment of:
 - Diabetic retinopathy including;
 - Nonproliferative retinopathy
 - Macular edema
 - Proliferative retinopathy
 - Retinal Tears, Detachments and Holes
 - Lattice degeneration
 - Age-related macular degeneration (AMD) with choroidal neovascularizations (CNV)
 - Retinopathy of prematurity
 - Sub-retinal (choroidal) neovascularization
 - Central and Branch Retinal Vein Occlusion
- Laser Trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation (TSCPC) for the treatment of glaucoma, including;
 - Primary open angle
 - Closed angle
 - Refractory Glaucoma (recalcitrant/uncontrolled)

VI Performance Standards

The The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]) accessories conforms with: Federal Regulations; the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems; and, International Harmonized Standards.

VI. Rationale for Substantial Equivalence

The Family of IRIDEX IQ Laser Systems shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Family of IRIDEX IQ Laser Systems is substantially equivalent to the predicate devices.

- 510(k) Summary Statement (continued)

VIII. Conclusion

The Family of IRIDEX IQ Laser Systems was found to be substantially equivalent to the predicate devices.

The Family of IRIDEX IQ Laser Systems share the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Iridex Corporation
% Mr. David Buzawa
Director Regulatory Affairs
1212 Terra Bella Avenue
Mountain View, California 94043-1824

AUG - 7 2008

Re: K071687

Trade/Device Name: Family of IRIDEX® IQ Laser Systems (IQ 532, IQ 577, IQ 630-670, IQ 810)

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: June 8, 2008

Received: June 9, 2008

Dear Mr. Buzawa:

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

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PS 103

510(k) Number (if known):

K071687

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 - › Retinopathy of prematurity
 - › Sub-retinal (choroidal) neovascularization
 - › Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
 - › Primary open angle/Closed angle

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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Indications for Use Statement - Continued

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 - proliferative and nonproliferative diabetic retinopathy;
 - choroidal neovascularization;
 - branch retinal vein occlusion;
 - age-related macular degeneration
 - retinal tears and detachments
 - retinopathy of prematurity
- ◆ Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

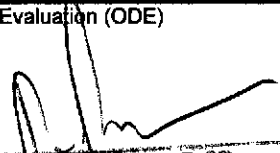
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Concurrence of CDRH, Office of Device Evaluation (ODE)


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

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- Retinal photocoagulation for the treatment of:
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 - Macular edema
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 - Lattice degeneration
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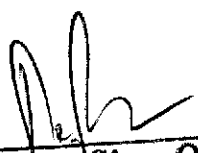
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