DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2017

Iridex Corporation
Gloria Dy
Regulatory Compliance Associate
1212 Terra Bella Avenue
Mountain View, CA 94043-1824

Re: K170718
Trade/Device Name:
Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 7, 2017
Received: March 9, 2017

Dear Gloria Dy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170718

Device Name
Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories

Indications for Use *(Describe)*
The Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulseTM or LongPulse TM 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
- 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 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

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 non-proliferative 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 glaucoma and open angle glaucoma

810nm
Ophthalmology:
Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following examples:
- 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 neovascularization (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)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Summary prepared on Date: April 27, 2017

510(k) Submitter/Holder:

Iridex Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Contact:
Gloria Dy
Regulatory Compliance Associate
Telephone: 650-605-8807
Fax: 650-962-0486
Email: gdy@iridex.com

Name of Device:
Trade Name: Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories

Common Name:	Laser Indirect Ophthalmoscope
Classification Name:	Laser Powered Surgical Instruments (and Accessories)

Predicate Device:

Trade Name:	Iridex TruFocus LIO+ Laser Indirect Ophthalmoscope
Common Name:	Laser Indirect Ophthalmoscope
Classification Name:	Laser Powered Surgical Instruments (and Accessories)
510(k) Number:	K071687
Manufacturer:	IRIS Medical Instruments, Inc. /Iridex Corporation

Device Description:
Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], and IQ 810 [810nm]), hand pieces, delivery devices & accessories is a delivery accessory used with the Iridex family of IQ laser systems (IQ532, IQ577, and IQ810). Iridex TruFocus LIO Premiere and the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories is a head-mounted diagnostic indirect ophthalmoscope which is used with a handheld lens to view and perform laser treatments on a patient's retina. It allows binocular visualization of the peripheral retina not easily viewed at the slit lamp and can be used to evaluate and treat patients, including infants, while they are in a supine position.

The LIO is a laser delivery device used to perform transpupillary laser photocoagulation during non-invasive ocular surgical procedures. The LIO is supplied non-sterile and is intended for reuse.

Variants of the device may relate to the style of headband, laser wavelength to be delivered, and the device to laser connector (i.e. RFID).

Intended Use:

Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), 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

- 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 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

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 non-proliferative 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 glaucoma and open angle glaucoma

810nm

Ophthalmology:

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

- 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 neovascularization (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)

Technological Characteristics:

The technological characteristics of the *Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], and IQ 810 [810nm]), hand pieces, delivery devices & accessories* are substantially equivalent to those of the predicate device, Iridex TruFocus LIO+ Laser Indirect Ophthalmoscope (K071687). ***See Table 8-1 below.***

Safety and Effectiveness:

The ISO 15004-2 testing proves that the proposed device design meets the accepted design standards for this type of device. Additionally, testing to the following standards IEC60601-2, IEC60601-1, IEC60825-1, IEC60601-2-22, IEC60601-1-6 and IEC62366 prove the safety and effectiveness of this device. A comparison of the technological characteristics proves that technological differences do not raise different questions of safety and effectiveness.

Conclusion:

The *Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], and IQ 810 [810nm]), hand pieces, delivery devices & accessories* was found to be substantially equivalent to the predicate device – Iridex TruFocus LIO+ (K071687).

The *Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories* shares identical indications for use, similar design features, and functional features with the predicate Iridex TruFocus LIO+ and therefore is substantially equivalent.

The *Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories* was found to be as safe, as effective and performs as well as or better than the predicate Iridex TruFocus LIO+ Laser Indirect Ophthalmoscope.

Table 8-1: Salient characteristics of the ***Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], and IQ 810 [810nm]), hand pieces, delivery devices & accessories*** and the predicate devices.

	Iridex TruFocus LIO Premiere with the Family of Iridex® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories	**Iridex TruFocus LIO+ Laser Indirect Ophthalmoscope**
510(k) applied and (predicate devices)	New device for which this Traditional 510(k) is being submitted	510(k) number: K071687
Classification Product Code	GEX – Powered Laser Surgical Instrument	GEX – Powered Laser Surgical Instrument
Intended Use	Retinal photocoagulation.	Retinal photocoagulation.
Type/Design	Indirect Ophthalmoscope Binocular (Headband mounted)	Indirect Ophthalmoscope Binocular (Headband mounted)
Treatment Wavelength	532nm, 577nm, 810nm	532nm, 577nm, 810nm, 630nm, 670nm

Eye Filter OD	6 @ 532 nm & 577nm, 2 @ 810 nm	6 @ 532 nm & 577nm, 2 @ 810 nm
Working Distance	370mm +/- 10mm	370mm +/- 10mm
Fiber Length	13'8"	13'8"
Aerial Spot Size	Standard LIO spot size: 1.1mm (0.043in) ±10% Large LIO spot size: 4.0mm (0.157in) ±10%	Standard LIO spot size: 1.1mm (0.043in) ±10% Large LIO spot size: 4.0mm (0.157in) ±10%
Illumination Source	LED Illumination light source standard with optional Halogen bulb	Halogen Lamp
Cooling System	Air Cooled	Air Cooled
Electrical	Heine rechargeable battery. Operates on 100-240VAC, 50/50Hz. Optional wall plug in charger.	6V DC from Iridex Laser console
Weight	≤ 1000gm (2.2 lbs.) with battery installed	1.2 lbs.