September 5, 2018

Iridex Corporation
Edward Sinclair
Vice President, Regulatory and Quality Affairs
1212 Terra Bella Avenue
Mountain View, California 94043-1824

Re: K181662
Trade/Device Name: Iridex TruFocus LIO Premiere
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: August 3, 2018
Received: August 6, 2018

Dear Edward Sinclair:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alexander Beylin -S
2018.09.05 18:03:14 -04'00'

for Malvina 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181662

Device Name
TruFocus LIO Premiere

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, 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)

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

Submitter Information

Company: Iridex Corporation
1212 Terra Bella Ave
Mountain View, CA 94043-1824
Phone: (650) 940-4700
Fax: (650) 355-1305
Establishment Registration No.: 2939653

Contact Person: Edward J. Sinclair
Vice President, Regulatory and Quality Affairs
Phone: (650) 940-4700
Fax: (650) 355-1305

Date Prepared: August 3, 2018

Device Name and Classification

Common Name:	Laser Indirect Ophthalmoscope
Proprietary Name:	Iridex TruFocus LIO Premiere™
Classification Name:	Laser Powered Surgical Instruments (and Accessories)
Product Code:	GEX
Regulation Number:	21 CFR§ 878.4810
Device Class:	II

Predicate Device

Company:	Iridex Corporation
Device:	Iridex TruFocus LIO Premiere™ (K170718)

Intended Use (Indications For Use)

The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications. The indications for use are described below:

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, 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)

Device Description

The Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope is a light combination and reflection viewing system used with the Iridex IQ/GL/SL/TX laser system families. The LIO combines a laser treatment beam from an Iridex laser source with the illumination beam of a Heine binocular indirect ophthalmoscope into a mixed optical beam used by a physician with a handheld ophthalmic examination (condensing) lens to enter a patient's pupil and to collect and view reflections by a patient's retina returned through the same pupil. It provides a portable alternative to patients who cannot be examined or treated with a fixed slit lamp adapter. The LIO is supplied non-sterile and is intended for reuse and worn on the physician's head to view and treat the patient's retina. The device can be used to evaluate and treat patients of all ages, including infants, in an office, operating room and ambulatory surgical center setting.

There are five models of the TruFocus LIO Premiere available that differ in the laser wavelength to be delivered, spot size, and the type of LIO-to-laser console connector, as listed in the table below.

Product No. (Model)	Description	Iridex Laser Console Compatibility	Spot Size	Connector Type
87300	TruFocus LIO Premiere, 532/810	OcuLight GL, TX, SL, SLx, IQ 532	350 µm	Resistive
87301	TruFocus LIO Premiere, 810	OcuLight SL, SLx	350 µm	Resistive
87302 (Large Spot)	TruFocus LIO Premiere, 810 LS	OcuLight SL, SLx	1400 µm	Resistive
87303	TruFocus LIO Premiere, 532	IQ 532	350 µm	RFID
87304	TruFocus LIO Premiere, 577	IQ 577	350 µm	RFID

Each LIO includes:
- Accessory Kit (PN 87526) comprised of a carry case (PN 87284), headband-mounted rechargeable battery (PN 87287), and a plug-in transformer (PN 87286). These accessories are also available for individual purchase.
- LIO instructions are provided in the form of an Operator Manual.
- Heine Omega 500 BIO instructions are included.
- Zero-diopter and Two-diopter lenses are included.

Other available options include:
- Extension cord for plug-in transformer
- Wall-mounted charging cradle

Key Functional Components

The TruFocus LIO Premiere contains the following hardware components:
- Adjustable headband
- Headband-mounted rechargeable battery
- Headband-mounted optics unit
- Fiber-optic cable with connector (resistive or RFID)
- Zero-diopter and Two-diopter lenses
- Plug-in transformer and extension cord
- Wall-mounted charging cradle
- Replaceable LED illumination bulb
- Standard carry case

Comparison of Technological Characteristics with the Predicate Device

The TruFocus LIO Premiere subject device is substantially equivalent to the TruFocus LIO Premiere predicate device (cleared by FDA in K170718 on May 3, 2017). The intended use, mechanism of action, and key components remain the same. There were no changes in the technological characteristics. A comparison of the significant technological characteristics, which are identical, is provided in the table below:

Characteristic	Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope *(Subject Device)*	Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope *(Predicate device cleared by K170718)*
Type/Design	Indirect Ophthalmoscope Binocular (Headband mounted)	Indirect Ophthalmoscope Binocular (Headband mounted)
Treatment Wavelength	532nm, 577nm, 810nm	532nm, 577nm, 810nm
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	LED Illumination light source standard with optional Halogen bulb
Cooling System	Air Cooled	Air Cooled
Electrical	Heine rechargeable battery. Operates on 100-240VAC, 50/50Hz. Optional wall plug in charger.	Heine rechargeable battery. Operates on 100-240VAC, 50/50Hz. Optional wall plug in charger.
Weight	≤ 1000gm (2.2 lbs.) with battery installed	≤ 1000gm (2.2 lbs.) with battery installed

Description of Changes

The Operator Manual (Instructions For Use) has been updated in order to (a) provide additional illustrations and clarification of the various adjustment controls, (b) clarify the patient treatment instructions showing how to position the illumination and aiming beams within the binocular field of view and how to position the condenser lens along the axis of the aiming beam, and (c) establish a separate section to provide instructions for use of the device in the binocular indirect ophthalmoscope (BIO) mode.

The submission also describes minor changes including a dimensional increase of a portion of the fiber optic cable assembly to improve attachment to molded clips at the top of the headband, an improved manufacturing process and new adhesive to enhance the bond reliability of the glass dust cover and cover frame used to shield the optics, and improvements to the aiming beam adjustment control cam surface finish resulting in a smoother actuation "feel" to the user.

Risk Analysis

A risk analysis was used to assess the impact of the cumulative effect of each device modification and the proposed modifications to the Operator Manual. The risk assessment methods comply with EN ISO 14971:2012 "*Medical devices – Application of risk management to medical devices*." The device and labeling changes described in this 510(k) submission were assessed for risk by reviewing the current Risk Management documentation for the TruFocus LIO Premiere device. The Hazard Analysis was reviewed and it was determined that no new hazards were introduced. The FMEA documents were reviewed to determine whether any risks were increased, reduced, or whether new risks were introduced as a result of the change (i.e., any difference in the occurrence or detectability of potential failure modes, or any new failure modes/potential causes). This assessment was performed by a qualified cross-functional team. The potential hazards were found to be sufficiently mitigated through the modified user instructions, device design, and change verification and validation to an acceptable level of risk. The potential benefits to patients outweigh the low residual risk of the modifications to the device and labeling.

Performance Data

In addition to verification and validation testing of the individual device changes, performance testing was conducted to validate the cumulative effect of device modifications and changes to the Operator Manual (the user instructions). A test procedure was developed to subject a sample size of 25 modified TruFocus LIO Premiere devices to a "simulated use" validation test following the modified Operator Manual. This test was designed to verify that when following the updated operator manual, the user could properly align and operate the device (e.g., the illumination and aiming/treatment beams would pass through the 20-diopter condensing lens and concentrically enter the simulated pupil plane using a pupil size of 6 mm in diameter, and achieve proper alignment of the internal illumination and aiming/treatment beam mirrors as well as illumination and aiming beam travel within the binocular field of view by using the adjustment control knobs). All units passed the simulated use test.

Conclusions

The modified TruFocus LIO Premiere device is as safe and effective as, and is substantially equivalent to, the predicate device.