March 23, 2022

Iridex Corporation
Bill Hyatt
Director of Regulatory Affairs
1212 Terra Bella Ave.
Mountain View, California 94043

Re: K213592
Trade/Device Name: Iridex 810 Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: February 18, 2022
Received: February 22, 2022

Dear Bill Hyatt:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain, Ph.D.
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213592

Device Name
Iridex 810 Laser System

Indications for Use *(Describe)*

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

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)	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

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; K213592

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: Bill Hyatt
Director, Regulatory Affairs
Phone: (650) 605-8727
Fax: (650) 940-4710

Date Prepared: March 21, 2022

Device Name and Classification

Common Name: Ophthalmic Laser, Powered Laser Surgical Instrument
Proprietary Name: Iridex 810 Laser
Classification Name: Laser, Ophthalmic
Product Code: HQF
Regulation Number: 21 CFR 886.4390
Device Class: II

Added Compatible Delivery Device:
Company: Iridex
Device C-Probe Delivery Device

Predicate Device

Laser Console
Company: Iridex Corporation
Device: Iridex 810 Laser (K202760)

Delivery Device
Company: Iridex Corporation
Device: MicroPulse P3 Delivery Device (K202760, K162416, K143154)

Intended Use (Indications for Use)

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

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)	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

Device Description

The Iridex 810 Laser system is comprised of a laser console with footswitch and an optical fiber delivery device. The laser console contains two laser diodes (810 nm for Treatment and 650 nm for Aiming beam), imaging optics, power supply, control electronics, and software/embedded firmware (with microprocessor). Lasing can only be initiated from the footswitch.

Optical fiber Delivery Devices are provided separately. The following tables shows compatible delivery devices.

Delivery Device Compatibility with Iridex 810 Laser

	Compatibility with Iridex 810 Laser (SUBJECT Device)			Compatibility with Iridex 810 Laser (PREDICATE Device)		
Delivery Device	**CW-Pulse**	**MicroPulse**	**LongPulse***	**CW-Pulse**	**MicroPulse**	**LongPulse***
EndoProbe Handpieces	●	●		●	●	
G-Probe (cleared under K162416)						
• G-Probe Standard	●			●		
• G-Probe Illuminate	●			●		
• TS-600 for Veterinary Use	●			●		
Laser Indirect Ophthalmoscopes (LIO)						
Iridex LIO Plus (Single-Mirror)						
• Standard 810 nm	●	●		●	●	
• Dual 810/532 nm	●	●		●	●	
• Large Spot 810 nm	●		●	●		●
TruFocus LIO Premiere (Dual Mirror)						
• Standard 810 nm	●	●		●	●	
• Dual 810/532 nm	●	●		●	●	
• Large Spot 810 nm	●		●	●		●
MicroPulse P3 (MP3) Probe Family (cleared under K162416)		●			●	
Operating Microscope Adapter (OMA)	●		●	●		●
Slit Lamp Adapters (SLA)						
• Standard 810 nm	●	●		●	●	
• Large Spot 810 nm	●		●	●		●
C-Probe (SUBJECT Compatible Delivery Device)	●					

* "LongPulse" is a function of Continuous Wave distinguished for marketing purposes to identify Continuous Wave exposure durations in excess of 9 seconds for large spot delivery devices. The proposed Iridex 810 Laser Operator Manual may not identify "LongPulse" but retains and identifies the function through Continuous Wave exposure durations in excess of 9 seconds for large spot delivery devices.

Comparison of Technological Characteristics with the Predicate Device

There are no proposed technology/engineering/performance nor materials changes to the currently marketed SUBJECT Laser Console Device.

The proposed change to the currently marketed SUBJECT Laser Console that is the subject of this special 510(k) is the following addition of an extended range of compatible delivery devices:

- Addition of a compatible delivery device, the Iridex C-Probe Delivery Device, which is a modification to the Iridex MicroPulse P3 Delivery Device. The C-Probe is an identical probe design to the MicroPulse P3 Delivery Device (MP3Probe) but with a unique RFID Tag to allow the laser system to recognize the probe as separate from the MP3 Probe and to inform the laser that the probe is used in Continuous Wave (CW) mode. Additionally, the handle of the C-Probe handle (no potential for patient contact) is the same design and materials as the MP3, but a different color to allow differentiation between the Iridex C-Probe Delivery Device and the MP3.

The following table provides a comparison of Technological Characteristics of the SUBJECT device (Iridex 810 Laser) including the SUBJECT compatible delivery device (Iridex C-Probe Delivery Device) to the PREDICATE Devices (Iridex 810 Laser; Iridex MicroPulse P3 Delivery Device). The technological characteristics of the SUBJECT device (laser console and compatible delivery device) are substantially equivalent to those of the PREDICATE device (laser console and compatible delivery device).

<table>
<tr><th>Characteristic</th><th>Iridex 810 Laser
(Predicate Device)</th><th>Iridex 810 Laser
(Subject Device)</th><th>Bearing on Substantial Equivalence</th></tr>
<tr><td colspan="4">Intended Use and Indications for Use</td></tr>
<tr><td>Intended Use and Indications for Use</td><td>Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other diode laser treatments. The following are examples of applications for the Iridex 810 Laser system.
<table>
<tr><th>Condition</th><th>Treatment</th></tr>
<tr><td>Diabetic Retinopathy
Nonproliferative Retinopathy
Macular Edema
Proliferative Retinopathy</td><td>Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments</td></tr>
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</table></td><td>Identical (no change)</td><td>Substantially Equivalent</td></tr>
<tr><td>Where the device is used</td><td colspan="2">Physician’s office, hospital operating room and ambulatory surgical center setting hospital, eye clinic or doctor’s exam room</td><td>Substantially Equivalent</td></tr>
</table>

510(k) SUMMARY; K213592 (continued)

Characteristic	Iridex 810 Laser (Predicate Device)	Iridex 810 Laser (Subject Device)	Bearing on Substantial Equivalence
Principles of Operation (technology)			
Technological Characteristics	The light energy delivered for treatment is from an 810 nm semiconductor laser source, with up to 5 W of output power, with an NA of 0.11 The light is delivered to the treatment site with fiber optic treatment probes The power source for the console is standard utility outlets	Identical (no change)	**Substantially Equivalent**
Design/Technological Characteristics			
Operating Principles	A laser console that plugs into standard utility outlets, connects to a footswitch for activation control and uses a delivery probe attached to the probe port to deliver the light. The console has a user interface to adjust system settings.	Identical (no change)	**Substantially Equivalent**
Design Characteristics	Hardware: A sheet metal enclosure with front bezel and back panel. An approved power supply, control board, diode driver, diode, user interface, power cord and foot switch Repetition rate: <50 Hz Laser activation: Footswitch Cooling System: Air Cooled	Identical (no change)	**Substantially Equivalent**
Output Mode	Continuous-Wave (including LongPulse duration) and MicroPulse	Identical (no change)	**Substantially Equivalent**
Electrical VAC	100-240 VAC, 50/60 Hz	Identical (no change)	**Substantially Equivalent**
Electrical Current	< 4 amps	Identical (no change)	**Substantially Equivalent**
User Interface	Touchscreen with Keyboard, Knobs on Laser Console, Remote Control, Footswitch	Identical (no change)	**Substantially equivalent**
Laser Activation	Footswitch	Identical (no change)	**Substantially Equivalent**
Performance			
Treatment wavelength (Nominal)	810 nm Infrared (IR) Diode	Identical (no change)	**Substantially Equivalent**
Aiming beam wavelength (Nominal)	650 nm	Identical (no change)	**Substantially Equivalent**
Maximum treatment laser power	3 W	Identical (no change)	**Substantially Equivalent**
Continuous Wave duration	10 ms-10 s	Identical (no change)	**Substantially Equivalent**
MicroPulse duration	100 µs – 1000 µs	Identical (no change)	**Substantially Equivalent**

Characteristic	Iridex 810 Laser (Predicate Device)	Iridex 810 Laser (Subject Device)	Bearing on Substantial Equivalence
Compatibility			
Compatible Delivery Devices	EndoProbe® Handpieces G_Probe® • G-Probe Standard • G-Probe Illuminate • TS-600 for Veterinary Use Laser Indirect Ophthalmoscopes (LIO) Iridex® LIO Plus (Single-Mirror) • Standard 810 nm • Dual 810/532 nm • Large Spot 810 nm TruFocus LIO Premiere® (Dual-Mirror) • Standard 810 nm • Dual 810/532 nm • Large Spot 810 nm MicroPulse P3® Probe Family Operating Microscope Adapter (OMA) Slit Lamp Adapters (SLA) • Standard 810 nm • Large Spot 810	Identical with the addition of the Iridex C-Probe Delivery Device	The C-Probe delivery device, which is a modified MicroPulse P3 delivery device, is added. **Substantially Equivalent**
Materials			
Materials	Sheet metal, approved plastic for the bezel material, standard electronics, laser diode. No liquids or hazardous materials	Identical (no change)	**Substantially Equivalent**
Packaging & Sterilization			
Packaging & Sterilization	The Iridex 810 Laser Console is supplied non-sterile. Shipping packaging has been designed to safely transport the device to end user facility	Minor change to packaging design and materials validated per ISTA 3A	**Substantially Equivalent**
Comparison of C-Probe and MicroPulse P3 Delivery Devices			
Characteristic	**Iridex MicroPulse P3 Delivery Device (Predicate Device - Compatible Delivery Device)**	**Iridex C-Probe Delivery Device (Subject Device)**	**Bearing on Substantial Equivalence**
C-Probe design compared to MicroPulse P3 Probe design	• Compatible with the Iridex 810 Laser Console • Handheld fiber optic, Contact plate is concave with no fiber optic protrusion • Biocompatible materials • RFID Code enables MicroPulse mode	• Compatible with Iridex 810 Laser • Identical design (including optic and contact plate) • Identical materials. Different color handle, which has no potential patient contact. • RIFD code enables Continuous Wave mode	**Substantially Equivalent** Changes made for physician preference to use Continuous Wave Mode and to differentiate between MicroPulse P3 and C-Probe Delivery Devices.
Packaging & Sterilization	The compatible MicroPulse P3 Delivery Device is supplied sterile.	Identical (no change)	**Substantially Equivalent** Changes made for physician preference to use Continuous Wave Mode

Performance Data

The following table summarizes nonclinical testing relevant to the Iridex 810 Laser System (Console and Compatible Delivery Devices) in accordance with the requirements of the design control regulations and established quality assurance procedures. Other than the packaging testing, which is updated to current ISTA 3A guidelines, Verification and Validation method(s) and results are unchanged from those data submitted in K202760; and those data continue to apply to the SUBJECT device. Clinical testing was not required for this product change.

Verification/ Validation Method(s)	Acceptance Criteria	Summary of Results
IEC 60601-1 Electrical Safety	Meet appliable clauses of IEC 60601-1	**PASS**. Device meets requirements of appliable clauses of IEC 60601-1
IEC 60601-2-22 Laser Safety	Meet all appliable IEC 60601-2-22 test items except for EMC, Biocompatibility	**PASS**. Device meets requirements of appliable clauses of IEC 60601-2-22.
IEC 60825-1 Laser Safety	Meet appliable IEC 60825-1 requirements	**PASS**. Device meets IEC 60825-1 Requirements
IEC 60601-1-2 EMI/EMC	Meet IEC 60601-1-2 Requirements	**PASS**. The unit met the requirements of appliable clauses of IEC 60601-1-2.
IEC 60601-1-6:2010, AMD1:2013 (Usability)	Meet the requirements of the appliable clauses IEC 60601-1-6	**PASS**. Device meets requirements of appliable clauses of IEC 60601-1-6
IEC 62304, Medical device software, Software life-cycle processes	Software lifecycle processes and activities meet requirements of appliable clauses of IEC 62304	**PASS** Software lifecycle processes and activities meet IEC 62304 Requirements
Shipping and Packaging Testing	Meet ISTA 3A Testing and Acceptance Requirements for: • Preconditioning • Atmospheric Conditioning • Shock Test • Random Vibration With and Without Top Load • Random Vibration Under Low Pressure – Truck Portion • Random Vibration Under Low Pressure – Air Portion • Shock Test Meet internal Iridex performance specifications pre- and post-conditioning testing.	**PASS.** All 5 units passed pre and post ISTA-3A testing (Westpak testing) and Pre-and Post-conditioning Testing (Iridex testing).

Conclusions

The Iridex 810 Laser (SUBJECT device) shares identical Intended Use, Indications for Use, Principles of Operation (technology) including energy source, Design/Technological Characteristics, and Performance, as the PREDICATE model of the Iridex 810 Laser, all of which do not raise new questions of safety and effectiveness.

There are no design differences between the proposed Iridex C-Probe Delivery Device (SUBJECT compatible device) and the currently marketed Iridex MicroPulse P3 Probe (PREDICATE compatible device), with the exception that a new RFID tag will communicate with the connected laser console to only allow use of the C-Probe in Continuous Wave mode rather than in MicroPulse mode, which is currently the mode used by the MicroPulse P3 delivery device. Since the PREDICATE laser console currently accepts delivery devices that use Continuous Wave mode, the change does not raise new questions of safety and effectiveness.

The conclusions drawn from the performance testing of the proposed SUBJECT device (Iridex 810 Laser Console) demonstrate substantial equivalence compared to the legally marketed predicate device.