October 21, 2020

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

Re: K202760
Trade/Device Name: Iridex 810 Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: September 16, 2020
Received: September 21, 2020

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,

for LT Charles Chiang
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202760

Device Name
Iridex 810 Laser

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
K202760

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:	October 20, 2020

Device Name and Classification

Common Name:	Ophthalmic Laser, Powered Laser Surgical Instrument
Proprietary Name:	Iridex 810 Laser
Classification Name:	Laser, Ophthalmic
Product Code:	HQF, GEX
Regulation Number:	21 CFR 886.4390, 21 CFR 886.4810
Device Class:	II

Predicate Device

Company:	Iridex Corporation
Device:	OcuLight SL/SLx, Model # 13030 (K020374)

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

Delivery Device	CW-Pulse	MicroPulse
Slit Lamp Adapter (SLA)	•	•
Large Spot Slit Lamp Adapter (LS-SLA)	•	
TruFocus LIO+	•	•
Large Spot TruFocus LIO+	•	
Endoprobe Family	•	•
G Probe	•	
Operating Microscope Adapter (OMA)	•	
MicroPulse P3 (MP3) Family (cleared under K162416)		•
G Probe and G Probe Illuminate (cleared under K162416)	•	

Comparison of Technological Characteristics with the Predicate Device

The Iridex 810 Laser (SUBJECT device) is modified from the PREDICATE device to address component obsolescence and to update the user interface to include a color touchscreen (replace LED interface) with a keyboard. Additionally, the range of compatible delivery devices was increased to include delivery devices have been marketed subsequent to the introduction of the PREDICATE device.

The following table provides a comparison of Technological Characteristics of the SUBJECT device (Iridex 810 Laser) to the PREDICATE Device (Iris Medical OcuLight SL/SLx). The technological characteristics of the SUBJECT device (Iridex 810 Laser) are substantially equivalent to those of the predicate device.

<table>
<tr><th>Characteristic</th><th>OcuLight SLx
(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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<tr><td>Central and Branch Retinal Vein Occlusion</td><td>PRP; Focal and Grid Laser Treatments</td></tr>
</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; K202760 (continued)

Characteristic	OcuLight SLx (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 810nm semiconductor laser source, with up to 5W 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: <50Hz Laser activation: Footswitch Cooling System: Air Cooled	Identical (no change)	**Substantially Equivalent**
Output Mode	CW (including LongPulse duration) and MicroPulse	Identical (no change)	**Substantially Equivalent**
Electrical VAC	100-240VAC, 50/50Hz	Identical (no change)	**Substantially Equivalent**
Electrical Current	<4amps	Identical (no change)	**Substantially Equivalent**
User Interface	Knobs on Laser Console, Remote Control, Footswitch	Touchscreen with Keyboard, Knobs on Laser Console, Remote Control, Footswitch	Addition of a touchscreen is for user convenience, no change to performance. **Substantially equivalent**
Laser Activation	Footswitch	Identical (no change)	**Substantially Equivalent**
Performance			
Treatment wavelength (Nominal)	810nm 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	10ms-10s	Identical (no change)	**Substantially Equivalent**
MicroPulse duration	10us – 1000us	Identical (no change)	**Substantially Equivalent**

Characteristic	OcuLight SLx (Predicate Device)	Iridex 810 Laser (Subject Device)	Bearing on Substantial Equivalence
Compatible Delivery Devices	IR Laser Indirect Ophthalmoscope (LIO) Large Spot (LS) LIO Dual LIO EndoProbes G-Probe / TS-600 MicroPulse P3 Family Slit Lamp Adapter (SLA) LS SLA Symphony SLA Symphony 2 SLA Operating Microscope Adapter (OMA)	IR Laser Indirect Ophthalmoscope (LIO) Large Spot (LS) LIO Dual LIO EndoProbes DioPexy Probe G-Probe / TS-600 Slit Lamp Adapter (SLA) LS SLA Symphony SLA Symphony 2 SLA Operating Microscope Adapter (OMA)	The MicroPulse P3 Family of probes and the G-Probe Illuminate probes are added, both cleared for use with other Iridex 810 Laser consoles under K162416. The DioPexy probe has been discontinued and so the subject device does not identify compatibility to the DioPexy. **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 device is supplied non-sterile. Shipping packaging has been designed to safely transport the device to end user facility	Identical (no change)	**Substantially Equivalent**

Performance Data

The following table summarizes nonclinical testing performed on the Iridex 810 Laser System in accordance with the requirements of the design control regulations and established quality assurance procedures. Clinical testing was not required for this product change.

510(k) SUMMARY; K202760 (continued)

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

510(k) SUMMARY; K202760 (continued)

Verification/ Validation Method(s)	Acceptance Criteria	Summary of Results
Shipping and Packaging Testing: ISTA 1A Procedure: • Vibration, Fixed Displacement Performed as follows: 10-500 Hz 30 minutes/axis, three axes • Shock Drop Performed as follows: 24" Drop on Corner, Edges (1-3) and Face (1-6) Power measurement (at 50% Duty Cycle), per product release test procedures. Measurement of current, per product release test procedures. Visual Inspection, per product release test procedures. Product functional inspection, per product release test procedures	ISTA 1A Procedure is Performed Measurement of console power (at 50% Duty Cycle) conforms to product release specifications in pre- and post-ISTA 1A Procedure testing. Measurement of console current in system conforms to product release specifications in pre- and post-ISTA 1A Procedure testing and demonstrates no significant change post-1A Procedure testing. Product and packaging appearance conform to product release specifications in pre- and post-ISTA 1A Procedure testing and are not observed to be adversely affected by ISTA 1A Procedure testing. Product functions, including console and footswitch interaction conform to product release specifications in pre- and post-ISTA 1A Procedure testing and are not observed to be adversely affected by ISTA 1A Procedure testing.	**PASS**. Observed Console Power Measurements, Console Current Measurement, Product and Packaging Appearance and Product Function performed pre- and post- ISTA 1A Procedure Testing passed product release specifications and were not adversely affected by ISTA 1A Procedure testing.

Conclusions

The Iridex 810 Laser shares identical indications for use and similar design and functional features with the predicate device. The differences between the Iridex 810 Laser and the OcuLight SLx devices do not affect the safety and effectiveness of the Iridex 810 Laser device when used as labeled. Therefore, the Iridex 810 Laser is substantially equivalent to the predicate device.