February 23, 2023

Iridex Corporation
Mari Iwamoto, PhD
Regulatory Affairs Specialist
1212 Terra Bella Ave.
Mountain View, CA 94043

Re: K230228
Trade/Device Name: Iridex® 532 Laser; Iridex® 577 Laser; Iridex® Laser (532 nm and 577 nm models)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: January 24, 2023
Received: January 27, 2023

Dear Mari Iwamoto, PhD:

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,

J Angelo Green -S

for Tieuvi Nguyen, Ph.D.
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)*
K230228

Device Name
Iridex® 532 Laser
Iridex® 577 Laser
Iridex® Laser (532 nm and 577 nm models)

Indications for Use *(Describe)*
The Iridex® Laser Console (532 model and 577 model) are solid state lasers that are used to deliver laser energy in either continuous wave pulse (CW-pulse) or MicroPulse® mode, for ophthalmic applications (532 and 577 models) and for Ear, Nose, and Throat (Otolaryngology) applications (532 model only).

Iridex® 532 Laser
The Iridex® 532 Laser is indicated for use in soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, ear, nose and throat (ENT)/otolaryngology, and ophthalmology as follows:

Ophthalmology
Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty including:
- Retinal photocoagulation (RPC) for the treatment of
  - o Diabetic retinopathy, including:
    - Nonproliferative retinopathy
    - Macular edema
    - Proliferative retinopathy
  - o Retinal tears and detachments
  - o Lattice degeneration
  - o Age-related macular degeneration (AMD)
  - o Retinopathy of prematurity
  - o Sub-retinal (choroidal) neovascularization
  - o Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
  - o Primary open angle/Closed angle

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

Iridex® 577 Laser
The Iridex® 577 Laser is indicated for use in soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialty of ophthalmology as follows:

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:
  - o Proliferative and nonproliferative diabetic retinopathy
  - o Choroidal neovascularization
  - o Branch retinal vein occlusion
  - o Age-related macular degeneration (AMD)
  - o Retinal tears and detachments
  - o Retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

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; K230228

Submitter Information

Company:	Iridex Corporation 1212 Terra Bella Ave Mountain View, CA 94043-1824 Phone: (650) 940-4700 Fax: (650) 940-4710 Establishment Registration No.: 2939653
Contact Person:	Mari Iwamoto, PhD Specialist, Regulatory Affairs Phone: (650) 605-8727 Fax: (650) 940-4710

Date Prepared: February 21, 2023

Device Name and Classification

Common Name:	Ophthalmic Laser, Powered Laser Surgical Instrument
Proprietary Name:	Iridex® 532 Laser, Iridex® 577 Laser, Iridex® Laser (532 and 577 nm models)
Classification Name:	Laser, Ophthalmic Powered Laser Surgical Instrument
Product Code:	HQF GEX
Regulation Number:	21 CFR 886.4390 21 CFR 878.4810
Device Class:	II

Predicate Device

Laser Console

Company:	Iridex Corporation
Device:	Collectively: Family of IRIDEX IQ® Laser Systems (IQ532, IQ577) (K071687) Individual Models: Iridex IQ 532® Laser System, Iridex IQ 577® Laser System

510(k) SUMMARY; K230228 (continued)

Intended Use (Indications for Use)

The Iridex® Laser Console (532 model and 577 model) are solid state lasers that are used to deliver laser energy in either continuous wave pulse (CW-pulse) or MicroPulse® mode, for ophthalmic applications (532 and 577 models) and for Ear, Nose, and Throat (Otolaryngology) applications (532 model only).

Indications for Use

The **Iridex 532 Laser** is indicated for use in soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

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

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

The **Iridex 577 Laser** is indicated for use in soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialty of ophthalmology as follows:

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 (AMD)
  - Retinal tears and detachments
  - Retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Device Description

The Iridex 532/577 Laser consoles are solid state lasers that are used to deliver laser energy in continuous wave and MicroPulse® for ophthalmic applications and (for 532 only) ear, nose, and throat (ENT) / otolaryngology applications. The Iridex® 532 Laser delivers a 532 nm wavelength (green) laser emission, and the Iridex® 577 Laser delivers a 577nm wavelength (true-yellow) laser emission.

The Iridex 532 Laser and the Iridex 577 Laser systems are comprised of a laser console with footswitch and an optical fiber delivery device. Each laser console model contains two laser diodes as follows:

- Iridex 532 Laser: 532 nm for Treatment and 650 nm for Aiming beam
- Iridex 577 Laser: 577 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 SUBJECT Iridex® 532 Laser and Iridex® 577 Laser

	Iridex® 532 Laser		Iridex 577® Laser	
Delivery Device	**CW-Pulse**	**MicroPulse**	**CW-Pulse**	**MicroPulse**
EndoProbe	●		●	
Laser Indirect Ophthalmoscopes (LIO)				
• Iridex LIO Plus (Single-Mirror)	●		●	
• TruFocus LIO Premiere (Dual Mirror)	●		●	
TxCell™ Scanning Laser Delivery System	●	●	●	●
Slit Lamp Adapters (SLA)	●	●	●	●
ENT Devices	●			

Comparison of Technological Characteristics with the Predicate Device

The following table provides a comparison of Technological Characteristics of the SUBJECT device (Iridex® 532 Laser and Iridex® 577 models) to the PREDICATE Devices (Iridex IQ 532® Laser System, Iridex IQ 577® Laser System).

The technological characteristics of the SUBJECT device (laser console) are substantially equivalent to those of the PREDICATE device (laser console and compatible delivery device).

510(k) SUMMARY; K230228 (continued)

Characteristic	Family of IRIDEX IQ® Laser Systems, IQ532, IQ577 models (PREDICATE Device)	Iridex 532 Laser / Iridex 577 Laser (Subject Device)	Bearing on Substantial Equivalence
Intended Use and Indications for Use			
Intended Use and Indications for Use	The Iridex® 532 Laser and Iridex® 577 Laser and the hand pieces, delivery devices and accessories that are used with them to deliver laser energy in either CW-pulse or MicroPulse mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of ear, nose and throat (ENT)/otolaryngology, and ophthalmology as follows: **532 nm** 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: o Diabetic retinopathy, including: ▪ Nonproliferative retinopathy ▪ Macular edema ▪ Proliferative retinopathy o Retinal tears and detachments o Lattice degeneration o Age-related macular degeneration (AMD) o Retinopathy of prematurity o Sub-retinal (choroidal) neovascularization o Central and branch retinal vein occlusion • Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including o Primary open angle/Closed angle **577 nm** 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: o Proliferative and nonproliferative diabetic retinopathy; o Choroidal neovascularization; o Branch retinal vein occlusion; o Age-related macular degeneration (AMD); o Retinal tears and detachments; o Retinopathy of prematurity; • Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma	Identical (no change)	**Substantially Equivalent**

510(k) SUMMARY; K230228 (continued)

Characteristic	Family of IRIDEX IQ® Laser Systems, IQ532, IQ577 models (PREDICATE Device)	Iridex 532 Laser / Iridex 577 Laser (Subject Device)	Bearing on Substantial Equivalence
Where the device is used	Physician's office, hospital operating room and ambulatory surgical center setting hospital, eye clinic or doctor's exam room	Identical (no change)	**Substantially Equivalent**
Principles of Operation (technology)			
Technological Characteristics	The light energy delivered for treatment is from a 532 nm (for IQ 532 Laser) or 577 nm (for IQ 577 Laser) semiconductor laser source, with up to 5 W of output power. The light is delivered to the treatment site with fiber optic treatment probes and accessories. 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/accessory 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, laser module driver, laser module, user interface, power cord and foot switch. Laser activation: Footswitch Cooling System: Air Cooled	Identical (no change)	**Substantially Equivalent**
Output Mode	Continuous-Wave and MicroPulse	Identical (no change)	**Substantially Equivalent**
Electrical VAC	100-240 VAC, 50/60 Hz	Identical (no change)	**Substantially Equivalent**
Electrical Current	< 3 amps	Updated to meet regulatory requirements	**Substantially Equivalent**
User Interface	Touchscreen with Keyboard, Knobs on Laser Console, Remote Control, Footswitch	Identical, but Remote Control is not planned to be provided	**Substantially equivalent**
Laser Activation	Footswitch	Identical with addition of currently marketed wired footswitches (cleared in 510(k) K151890 and K160549)	**Substantially Equivalent**

510(k) SUMMARY; K230228 (continued)

Characteristic	Family of IRIDEX IQ® Laser Systems, IQ532, IQ577 models (PREDICATE Device)	Iridex 532 Laser / Iridex 577 Laser (Subject Device)	Bearing on Substantial Equivalence
Performance			
Treatment wavelength (Nominal)	For the 532 nm Laser: • 532 nm For the 577 nm Laser: • 577 nm	Identical (no change)	**Substantially Equivalent**
Aiming beam wavelength (Nominal)	635 nm laser diode. User-adjustable	Identical (no change)	**Substantially Equivalent**
Maximum laser power	5 W (treatment)	Reduced Maximum Laser Power to 2.5 W	**Substantially Equivalent**
Treatment laser power	For the Iridex 532 Laser: 50 – 2500 mW (delivered), depending on delivery device. XP Option: 0 - 5000 mW (delivered) For the Iridex 577 Laser: 50 – 2000 mW (delivered), depending on delivery device. Option to maximum of 2.5 W	For the Iridex 532 Laser: 50 – 2500 mW (delivered), depending on delivery device. For the Iridex 577 Laser: 50 – 2000 mW (delivered), depending on delivery device. Option to maximum of 2.5 W Identical, however XP Option is not Offered	**Substantially Equivalent**
Maximum aiming beam power	< 1 mW (aiming)	Identical (no change)	**Substantially Equivalent**
Continuous Wave duration	10 ms – 10000 ms or CW to 60 seconds	Tightened the maximum CW Pulse, which remains within the original duration specification as follows: 10 ms – 3000 ms or CW to 60 seconds	**Substantially Equivalent**

Characteristic	Family of IRIDEX IQ® Laser Systems, IQ532, IQ577 models (PREDICATE Device)	Iridex 532 Laser / Iridex 577 Laser (Subject Device)	Bearing on Substantial Equivalence
MicroPulse duration	0.025 ms – 1.0 ms	Tightened the maximum MicroPulse duration, which remains within the original duration specification as follows: 0.05 ms – 1.0 ms	**Substantially Equivalent**
Compatibility			
Compatible Delivery Devices	EndoProbe® Handpieces Laser Indirect Ophthalmoscopes (LIO) • Iridex® LIO Plus (Single-Mirror) o Standard 532 nm (IQ 532 Laser) o Dual 810/532 nm (IQ 532 Laser) o Standard 577 nm (IQ 577 Laser) • TruFocus LIO Premiere® (Dual-Mirror) o Standard 532 nm (IQ 532 Laser) o Dual 810/532 nm (IQ 532 Laser) o Standard 577 nm (IQ 577 Laser) Slit Lamp Adapters (SLA) TxCell™ Scanning Laser Delivery System ENT Devices (IQ 532 Laser only)	Identical (no change)	**Substantially Equivalent**
Packaging & Sterilization			
Packaging & Sterilization	The IQ 532 and IQ 577 Laser Consoles are supplied non-sterile. Shipping packaging has been designed to safely transport the device to end user facility	The Iridex Laser (532 nm and 577 nm models) consoles are supplied non-sterile. Change to packaging design and materials are validated per ISTA 3A	**Substantially Equivalent**

Performance Data

The following table summarizes nonclinical testing to standards relevant to the Iridex® Laser (532 and 577 nm models) 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; K230228 (continued)

Verification/ Validation Method(s)	Acceptance Criteria	Summary of Results
Testing to External Standards (Testing Performed by External Test Houses)		
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 (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.** The test unit passed pre and post ISTA-3A testing (Westpak testing) and Pre-and Post-conditioning testing to specification (Iridex testing).

510(k) SUMMARY; K230228 (continued)

Verification/ Validation Method(s)	Acceptance Criteria	Summary of Results
Testing to Iridex Internal Specifications		
Treatment Beam Power Output Measured power output setting at 50, 250, 500, 1000, and 2000 mW (Iridex 532 and Iridex 577 models); 2500 mW (Iridex 532 model only)	Measured Power Output is Power Setting ±20%	**PASS**
Pulse Duration/Interval (MicroPulse Mode) Measured various combinations of Pulse Duration and Interval settings throughout and beyond claimed range	Measured Pulse Duration/Interval is Pulse Duration/Interval Setting ±10%	**PASS**
Pulse Duration/Interval (Continuous-Wave Mode) Measured various combinations of Pulse Duration and Interval settings throughout and beyond claimed range	Measured Pulse Duration/Interval is Pulse Duration/Interval Setting ±10%	**PASS**
Aiming Beam Power Output Measured power output at 0 mW and 0.7 mW setting	Measured Power Output observable throughout specified power range, ±0.2 mW nominal	**PASS**
Software Verification/Validation		
Software development and Software Verification and Validation tasks were performed consistent with IEC 62304 (Medical device software, Software lifecycle processes), and were found to meet the requirements of IEC 62304. Software V&V tasks were performed at each stage, previous V&V tasks revisited, or new V&V tasks initiated until acceptance or passing criteria were achieved for that particular task.	Each module within each of the five following Software V&V Domains must pass: 1) Product Info Domain 2) Essential (Basic) Function Domain 3) Setting Domain 4) Specials Domain 5) Accessories Domain	**QUALIFIED** Each module within the five Software V&V Domains passed: 1) Product Info Domain 2) Essential (Basic) Function Domain 3) Setting Domain 4) Specials Domain 5) Safety Domain The software performance meets the requirements of the software requirements specification.

510(k) SUMMARY; K230228 (continued)

Conclusions

The Iridex Laser (532 nm and 577 nm models) devices (SUBJECT devices) share identical Intended Use, Indications for Use, Principles of Operation (technology) including energy source, Design/Technological Characteristics, and Performance, as the IQ 532 and IQ 577 Laser Systems (PREDICATE device models), all of which do not raise new questions of safety and effectiveness.

The proposed SUBJECT device models are at least as safe and effective as the legally marketed predicate devices.