November 9, 2022

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

Re: K223132
Trade/Device Name: Iridex PASCAL® 532, Iridex PASCAL® 577, Iridex PASCAL® (532 nm and 577 nm models)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: September 23, 2022
Received: October 3, 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 -S

Anjana Jain, PhD
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)*
K223132

Device Name
Iridex PASCAL® 532, Iridex PASCAL® 577, and Iridex PASCAL® (532 nm and 577 nm models)

Indications for Use *(Describe)*
Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

(532nm)
• proliferative and non-proliferative diabetic retinopathy
• macular edema
• choroidal neovascularization associated with wet age-related macular degeneration
• age-related macular degeneration
• lattice degeneration
• retinal tears and detachments

(577nm)
• proliferative and non-proliferative diabetic retinopathy
• macular edema
• choroidal neovascularization associated with wet age-related macular degeneration
• age-related macular degeneration
• lattice degeneration
• retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

(532 nm and 577nm)
• iridotomy
• trabeculoplasty

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; K223132

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: November 09, 2022

Device Name and Classification

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

Predicate Device

Laser Console

Company:	Iridex Corporation
Device:	PASCAL® Synthesis™ Ophthalmic Scanning Laser System (K123542)

Intended Use

A laser system console with an integrated slit lamp. The system connects to the slit lamp to enable laser energy to be delivered through the slit lamp illumination path. The system may be used for standard single shot photocoagulation and laser scanning patterns.

The system enables the physician to deliver multiple laser spots with a single footswitch depression by automating the emission of laser light. The aiming beam displays the pattern, allowing the physician to place it in the appropriate location.

Indications for Use

Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

(532nm)

- proliferative and non-proliferative diabetic retinopathy
- macular edema
- choroidal neovascularization associated with wet age-related macular degeneration
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

(577nm)

- proliferative and non-proliferative diabetic retinopathy
- macular edema
- choroidal neovascularization associated with wet age-related macular degeneration
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

(532 nm and 577nm)

- iridotomy
- trabeculoplasty

Device Description

The Iridex PASCAL® (532 nm and 577 nm models) is an ophthalmic scanning laser system. **PASCAL** is an acronym for **Pa**ttern **SCA**n **L**aser. The system can perform single shot photocoagulation as is performed conventionally. In addition, the system is equipped with proprietary laser scanning technology that provides the user with the option to perform laser pattern scanning. This allows the user to place many laser treatment spots in a patient's eye rapidly by performing pattern scan laser photocoagulation. The system will scan user-selectable patterns of laser spots into a patient's eye.

The system includes a table for housing the laser module and associated electronics. A slit lamp is also integrated in the table enabling the interface to be at the base of the slit lamp, i.e., no external cabling. The table is smaller in size compared to prior versions to accommodate use in smaller rooms. In addition to single shot and pattern scanning the system also supports the use of a Laser Indirect Ophthalmoscope (LIO) with optical fiber port for connection of a LIO.

The system is available with either 532nm or 577nm laser emission.

Comparison of Technological Characteristics with the Predicate Device

A risk management analysis was conducted in accordance with standard EN ISO 14971.

The following table provides a comparison of Technological Characteristics of the SUBJECT device (Iridex PASCAL® 532 and Iridex PASCAL® 577) to the PREDICATE Device (PASCAL® Synthesis™ Ophthalmic Scanning Laser System).

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

Characteristic	PASCAL® Synthesis™ Ophthalmic Scanning Laser System (Predicate Device)	Iridex PASCAL® (532 nm and 577 nm models) (Subject Device)	Bearing on Substantial Equivalence
Intended Use and Indications for Use			
Intended Use and Indications for Use	Intended Use: A laser system console with an integrated slit lamp. The system connects to the slit lamp to enable laser energy to be delivered through the slit lamp illumination path. The system may be used for standard single shot photocoagulation and laser scanning patterns. The system enables the physician to deliver multiple laser spots with a single footswitch depression by automating the emission of laser light. The aiming beam displays the pattern, allowing the physician to place it in the appropriate location. Indications for Use: Intended for use in the treatment of ocular pathology in both the posterior and anterior segments. Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including: (532nm) • proliferative and non-proliferative diabetic retinopathy • macular edema • choroidal neovascularization associated with wet age-related macular degeneration • age-related macular degeneration • lattice degeneration • retinal tears and detachments (577nm) • proliferative and non-proliferative diabetic retinopathy • macular edema • choroidal neovascularization associated with wet age-related macular degeneration • age-related macular degeneration • lattice degeneration • retinal tears and detachments Intended for use in the treatment of ocular pathology in the anterior segment including: (532 nm and 577nm) • iridotomy • trabeculoplasty	Identical (no change) Note: **There is no proposed change with respect to Intended Use and Indications for Use**.	**Substantially Equivalent**

510(k) SUMMARY; K223132 (continued)

Characteristic	PASCAL® Synthesis™ Ophthalmic Scanning Laser System (Predicate Device)	Iridex PASCAL® (532 nm and 577 nm models) (Subject Device)	Bearing on Substantial Equivalence
Where the device is used	• Professional Healthcare Facility Environment • Physician offices, clinics, multiple treatment facilities, hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high	Identical (no change)	**Substantially Equivalent**
Design/Technological Characteristics			
Operating Principles	A laser system console with an integrated slit lamp. The system connects to the slit lamp to enable laser energy to be delivered through the slit lamp illumination path. The system may be used for standard single shot photocoagulation and laser scanning patterns The system enables the physician to deliver multiple laser spots with a single footswitch depression by automating the emission of laser light. The aiming beam displays the pattern, allowing the physician to place it in the appropriate location.	Identical (no change)	**Substantially Equivalent**
Laser Type	Optically Pumped Semiconductor Laser (OPSL) (Treatment) Laser Diode (Aiming)	Identical (no change)	**Substantially Equivalent**
Output Wavelength	• 532 nm or 577 nm (Treatment) • 635 nm (Aiming)	Identical (no change)	**Substantially Equivalent**
Output Mode	Continuous-Wave	Identical with addition of MicroPulse®	**Substantially Equivalent**
Electrical VAC	100-240 VAC, 50/60 Hz	Identical (no change)	**Substantially Equivalent**
Electrical Current	< 10 Amperes	Identical (no change)	**Substantially Equivalent**
User Interface	• Touchscreen LCD Control Panel, • Slit Lamp, • Micro Manipulator (slit lamp), • Power Knob (slit lamp), • 3D Controller (optional), • Footswitch (wired)	Identical with the following changes: • addition of Wireless Footswitch as an optional accessory, • the removal of 3D Controller as an option	**Substantially equivalent**
Laser Activation	Footswitch (wired)	Identical with addition of Wireless Footswitch as an optional accessory	**Substantially Equivalent**
Performance			
Treatment wavelength (Nominal)	• 532 nm for 532 model • 577 nm for 577 model	Identical (no change)	**Substantially Equivalent**
Aiming beam wavelength (Nominal)	635 nm	Identical (no change)	**Substantially Equivalent**
Power Output (mW)	• 0 to 2000 mW (Treatment) • Adjustable 0 to <1 mW (Aiming)	Identical (no change)	**Substantially Equivalent**
Duty Cycle	100%	Enable a variable Duty Cycle with no change to maximum duty cycle (i.e., no change to the maximum percentage of 100%)	**Substantially Equivalent**

Characteristic	PASCAL® Synthesis™ Ophthalmic Scanning Laser System (Predicate Device)	Iridex PASCAL® (532 nm and 577 nm models) (Subject Device)	Bearing on Substantial Equivalence
Pulse duration	10 ms to 1000 ms	Maintain maximum pulse (1000ms) while enabling the lower end of the pulse range. The enabled exposure time range is 0.05ms -1000ms	**Substantially Equivalent**
Pulse Interval	1, 1.5, 2, 3, 4, 5, 6, 7 and 8 Hz (single spot or LIO)	Identical (no change)	**Substantially Equivalent**
Pulse Counter	0 – 99,999	Identical (no change)	**Substantially Equivalent**
Laser Beam diameter	50, 100, 200, 400 µm (in air)	400 µm was replaced with 300 µm	**Substantially Equivalent**
Compatibility			
Compatible Delivery Devices	Laser Indirect Ophthalmoscopes (LIO)	Identical (no change)	**Substantially Equivalent**
Packaging & Sterilization			
Packaging & Sterilization	• Supplied non-sterile. • Shipping packaging has been designed to safely transport the device to end user facility	Change to packaging design and materials that was validated per ISTA 3B	**Substantially Equivalent**

Performance Data

The following table summarizes nonclinical testing relevant to the Iridex PASCAL® 532 and Iridex PASCAL® 577 in accordance with the requirements of the design control regulations and established quality assurance procedures.

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 60601-1-2 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 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 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 3B Testing and Acceptance Requirements for: • Climatic Conditioning-Package • Climatic Conditioning-Product • Atmospheric Preconditioning • Shock (First Sequence) • Vertical Vibration (Random Vibration with Top Load) • Shock (Second Sequence) Meet Iridex performance specifications pre- and post-conditioning testing.	**PASS.** Test unit passed ISTA-3B conditioning and testing (Westpak testing) Test unit passed Iridex performance testing Pre-and Post-conditioning (Iridex testing).

Conclusions

The Iridex PASCAL® (532 nm and 577 nm models) (SUBJECT device) shares identical Intended Use, Indications for Use, Principles of Operation (technology) including energy source, Design/Technological Characteristics, and Performance, as the PASCAL® Synthesis™ Ophthalmic Scanning Laser System (PREDICATE device), all of which do not raise new questions of safety and effectiveness.

The proposed SUBJECT device is at least as safe and effective as the legally marketed predicate device.