DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 29, 2016

Iridex Corporation
Ms. Kathy Maynor
Acting VP of Regulatory/Quality
1212 Terra Bella Avenue
Mountain View, CA 94043

Re: K162416
Trade/Device Name: Iridex Cyclo G6 Laser System, G-Probe Illuminate
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 27, 2016
Received: August 30, 2016

Dear Ms. Maynor:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)* ***K162416***

Device Name

Cyclo G6 Laser System with Illumination

Indications for Use *(Describe)*

The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm] [IRIDEX Cyclo G6 Laser System]) and the 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:

810nm (The IRIDEX Cyclo G6 Laser System)

Ophthalmology:

The IRIDEX® Cyclo G6™ Laser System and Probe Delivery Devices (G-Probe, G-Probe Illuminate, & MicroPulse® P3) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse (μP) treatment mode and indicated for the treatment of Glaucoma:

	Condition (Indicated	**Treatment (Intended Use)**	**CW/μP**
MicroPulse P3 Device	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral Cyclophotocoagulation (TSCPC) of the ciliary processes	μP
G-Probe & G-Probe Illuminate	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	CW

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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Section 8 – Special 510(k) Summary

I. General Information

Submitter:

Iridex Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Contact Person:
Kathy Maynor
kmaynor@iridex.com
352-586-3113

Summary Preparation Date: September 28, 2016

II. Names

Device Name(s): Cyclo G6 Laser System with Illumination

Primary Classification Name(s): Electrosurgical cutting and coagulation device and accessories

III. Predicate Devices

K143154 –Iridex Cyclo G6 Laser System

IV. Product Description

The Iridex Cyclo G6 is an 810nm (diode) ophthalmic laser comprised of the following main components:

- Main console containing the major electrical components, including:
  - Control Panel including control knobs (power, interval, duration or software assigned function), treat/standby button, and display;
  - Two delivery device fiber-optic connector ports (only one active at a time);
  - LIO illumination connection;
  - Smart key port for detecting/operating safety filters and/or accessory identification;
  - Emergency stop switch;
  - Key switch;
  - Connector ports for the footswitch, remote control, and power cord;
  - A treatment Footswitch (either wired, wireless, or wireless with PowerAdjust);
  - A Wired Remote Control that duplicates the control panel;
  - Delivery Accessories including G-Probe and MicroPulse P3 probe Handpieces, and the G-Probe Illuminate
  - Optional Cart/Stand

The laser system automatically enters the "Standby" mode after it is turned on and completes its internal "selftest". Laser emission is not possible until the user attaches the proper delivery device, selects the desired treatment settings, verifies eye safety filter status, places the system into "Ready", and depresses the footswitch.

The system has a primary display screen (power, interval, duration, pulse mode, aiming beam brightness, illumination brightness, treatment/standby toggle, counter reset) and additional screens for ancillary options (system volume, display contrast/brightness, preset selection (user defined/generated), aiming beam settings).

The user may adjust power, treatment duration, treatment interval, type of laser output mode (CW-pulse, MicroPulse), aiming beam brightness, illumination brightness, and reset the laser shot counter. Additionally, for some delivery devices the user may optionally select the on/off operation of the countdown timer on the display screen as well as the on/off function of the voice countdown.

The G-Probe Illuminate that is the subject of this 510(k) is a handheld fiber optic delivery device. It is intended to be used to perform transscleral cyclophotocoagulation of the ciliary processes. It is differentiated from the G-Probe described in earlier submissions by the incorporation of two additional optical fibers to provide white light transillumination of the optic globe. Such transillumination can aid probe placement by revealing the location of internal ocular structures such as the ciliary processes. The incorporation of this transillumination function into a multifunction probe offers the user similar functionality as a separate handheld transilluminator, with a more convenient setup that requires fewer hands or assistants to operate. It is provided as a sterile, single-use device.

V. Indications for Use

The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm] [IRIDEX Cyclo G6 Laser System]) and the 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:

810nm (The IRIDEX Cyclo G6 Laser System)

Ophthalmology:

The IRIDEX® Cyclo G6™ Laser System and Probe Delivery Devices (G-Probe, G-Probe Illuminate, & MicroPulse® P3) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse (µP) treatment mode and indicated for the treatment of Glaucoma:

	Condition (Indicated for)	Treatment (Intended Use)	CW/µP
MicroPulse P3 Device	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	µP
G-Probe & G-Probe Illuminate	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	CW

VI. Performance Testing

Clinical trial data was not required for this product change. This product change did not require any additional EMC (electromagnetic compatibility) or IEC 60601 safety testing. There were no software changes to the product.

The product change did require the following tests, which were successfully completed to the relevant standards:

Sterilization:
ISO 11135: 2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

Biocompatibility:
ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
ISO 10993-5: 2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for Irritation and Skin Sensitization

Illumination:
ISO 15004-2:2007 Ophthalmic Instruments -Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection

Shelf Life:
ASTM F1980-07:2011 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Transit Testing:
ASTM D4169-14 Standard Practice for Performance Testing of Shipping Containers

and Systems
ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packing Components for Testing
ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
BS EN ISO 11607-1: 2009 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

VII. Summary of Technological Characteristics

The technological characteristics of the Iridex Cyclo G6 laser are substantially equivalent to those of the predicate device.

Characteristic	**Iridex Cyclo G6 Laser System**	**K143154** Iridex Cyclo G6 Laser System
Product Code Regulation	General & Plastic Surgery • GEX, 21 CFR 878.4810	General & Plastic Surgery • GEX, 21 CFR 878.4810
Intended Use	Intended for use for the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory (see section V above)	Intended for use for the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory (see section V above)
Indications for Use	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes
Wavelength	810nm – Infrared (IR) Diode	810nm – Infrared (IR) Diode
Aiming beam	630-670 nm – red (nominal) – variable intensity from 0 to < 1.0 mW	630-670 nm – red (nominal) – variable intensity from 0 to < 1.0 mW
Power Watts	5W	5W
Pulse Duration (usec)	CW Pulse 10ms-10S MicroPulse (µP) 10µs-1000µs	CW Pulse 10ms-10S MicroPulse (µP) 10µs-1000µs

Characteristic	Iridex Cyclo G6 Laser System	**K143154** Iridex Cyclo G6 Laser System
Energy per pulse (mJ)	Variable: Determined by Power in Watts and time. Calculated by Joule = Watts x Time	Variable: Determined by Power in Watts and time. Calculated by Joule = Watts x Time
Output Mode	CW-Pulse, MicroPulse	CW-Pulse, MicroPulse
Repetition rate	<50 Hz	<50 Hz
Laser media	810 nm Diode Laser	810 nm Diode Laser
Illumination	420-700 nm	NA
User interface	Touch Screen, Knobs on Laser Console, Remote Control, Footswitch	Touch Screen, Knobs on Laser Console, Remote Control, Footswitch
Laser activation	Footswitch	Footswitch
Delivery devices, how supplied	Ordered with System or separately	Ordered with System or separately
Electrical requirements	100 to 240 VAC @ 50 to 60 Hz	100 to 240 VAC @ 50 to 60 Hz

VIII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Iridex Cyclo G6 Laser is substantially equivalent to the predicate device and is safe and effective for use for the various indications for use stated.

The changes that are the subject of this 510(k) were verified and validated in accordance with the Iridex design control procedures.

IX. Conclusion

The Iridex Cyclo G6 Laser was found to be substantially equivalent to the predicate device.

The Iridex Cyclo G6 Laser shares identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate device.