DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 15, 2017

Katalyst Surgical, LLC
Meryl Koch
Quality Assurance and Regulatory Affairs Manager
754 Goddard Avenue
Chesterfield, MO 63005

Re: K163632
Trade/Device Name: Katalyst Cyclophotocoagulation Probe
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: LQJ
Dated: May 3, 2017
Received: May 9, 2017

Dear Meryl Koch:

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,

Denise L. Hampton -S

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)*
K163632

Device Name
Katalyst Cyclophotocoagulation Probe

Indications for Use *(Describe)*
Katalyst Cyclophotocoagulation Probe is intended, when used with an infrared laser, for Transscleral Cyclophotocoagulation (TSCPC) of the ciliary process.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Manufacturer: Katalyst Surgical, LLC
754 Goddard Avenue
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636-399-0109 (phone)
636-787-0603 (fax)

Contact: Meryl Koch
Katalyst Surgical, LLC
636-536-5950 (phone)
636-787-0603(fax)
m.koch@katalystsurgical.com

Date Prepared: March 29th, 2017

Device Trade Name: Katalyst Cyclophotocoagulation Probe

Common Name: Katalyst Cycloprobe

Classification: 21 CFR886.4390; Lens, Surgical, Accessory, Ophthalmic Laser

Class: II

Product Code: LQJ

Indications for Use:
Katalyst Cyclophotocoagulation Probe is intended, when used with an infrared laser, for Transscleral Cyclophotocoagulation (TSCPC) of the ciliary process.

Device Description:
The Cycloprobe is a single use device sold sterile.

The Cycloprobe is made out of one fiberoptic, one laser machine connector, one handle for surgeon manipulation, one clear tip for placement on the eye, and a protective sheath over the fiber.

On the distal side, the fiberoptic is terminated by a connector that attaches to the laser machine. On the other side, it is terminated by a fiber that has a ball lens formed onto the end that protrudes slightly from the clear tip.

The connector configuration is chosen based on the surgeons' laser machine requirements. The total length of the device is 7 feet.

Predicate Devices:
The Katalyst Cyclophotocoagulation Probe was shown to be substantially equivalent to the previously cleared device, Iridex G-Probe approved within 510k K143154.

Substantial Equivalence:
Clinical Testing was not required to prove substantial equivalence. Bench testing performed between the candidate device and the predicate device indicates that the Katalyst Cyclophotocoagulation Probes are substantially equivalent to predicate devices.
The product required the following other tests which were completed successfully:

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 Irrigation and Skin Sensitization

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

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

Device Name	Katalyst Cycloprobe	Iridex G-Probe
Indications for Use	Identical	Identical
Target Population	Identical	Identical
Design	Similar	Similar
Optical Output	Identical	Identical
Materials	Identical	Identical
Performance	Identical	Identical
Sterility	Identical	Identical
Biocompatibility	Identical	Identical
Anatomical Sites	Identical	Identical
Human Factors	Identical	Identical
Energy Used and/or Delivered	Identical	Identical

Conclusion
The Katalyst Cyclophotocoagulation Probes were shown to be substantially equivalent to previously cleared devices with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.