DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 15, 2015

Ophthalmed LLC
Mr. Jay Mansour
Director , QA/RA
1050 Northfield Ct., Suite 280
Roswell, GA 30076

Re: K142830
Trade/Device Name: Ophthalmed Directional Laser Probes Models A207000, A807000 and A307000
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQB, HQF
Dated: September 22, 2014
Received: September 30, 2014

Dear Mr. Mansour:

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" (21CFR 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 yours,

Deborah L. Falls -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

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)*
K142830

Device Name
Ophthalmed Bending Laser Probes (Models A207000, A807000, and A307000)

Indications for Use *(Describe)*
The Ophthalmed Bending Laser Probes (Models A207000, A807000, and A307000) are indicated for performing laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery at an operating wavelength range from 500 to 1100 nm.

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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510k Summary

As required by 21 CFR 807.92

I. SUBMITTER

OPHTHALMED LLC.
1050 NORTHFIELD COURT, SUITE 280.
ROSWELL, GA 30076 USA.
Tel 770 777 6613
Fax 678 623 3765

Contact person: Jay Mansour
Date prepared: June 25, 2015

II. DEVICE

Name of device: Ophthalmed bending laser probes (Models A207000, A807000, and A307000)
Common or usual name: laser probe
Classification name: Ophthalmic photocoagulator
Regulatory class: II
Product code: HQB

III. PREDICATE DEVICE

510k number	Trade or Proprietary or Model Name	Manufacturer	Primary predicate device
K021696	LF20, LF25	OPHTHALMED LLC	Yes
K050807	LF100	OPHTHALMED LLC	No
K113857	Synergetics Directional Endo Ocular Laser Probe	SYNERGETICS	No
K121187	Katalyst laser probes	KATALYST SURGICAL	No

IV. DEVICE DESCRIPTION

This laser probe is made out of 8ft fiberoptic, terminated on one end with Alcon compatible (SMA905) laser connector, and on another side with a handpiece for holding and manipulation during surgery. For protection against damages, a flexible plastic jacket covers the length of the fiber.

The handpiece is terminated by a proximal stainless steel tubing that is 20, 23 or 25 gauge in size, and ending with a distal pre-curved PEEK memory tube that can change angle when activated by the sliding button on the handle side.

When the sliding button on the handle is advanced, an internal straightening tube advances into the distal pre-curved PEEK memory tube, thus causing a reduction of the angle of the pre-curved PEEK memory tube, down to zero degrees at the maximum sliding position,

allowing the selection of the desired angle during surgery. The maximum angle is 55 degrees for 20g and 23g, and 40 degrees for 25g.

This device allows to transmit laser energy from the laser source to the surgical site, facilitated by the aiming beam that is provided by the laser source. This device does not provide illumination and should not be used to illuminate the surgical site.

The user should refer to the instructions for use of the laser source, for information about the increments for power settings, duty cycle, and ranges and increments for timing and interval.

This device does not include any lenses, and there is no focal distance to define. The laser spot size at 4mm away is 1mm.

V. INDICATIONS FOR USE

The Ophthalmed Bending Laser Probes (Models A207000, A807000, and A307000) are indicated for performing laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery at an operating wavelength range from 500 to 1100 nm.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICE DEVICE:

Summary of technological characteristics of our device compared to predicate device, in design, material, chemical composition and energy source:

Design:

All predicate devices have the same main structure and functionality as our device: a fiber optic is terminated on one side via a laser connector that mates with a laser machine, and on the other side terminated by a tip that penetrates the eye so that the laser beam can reach into the surgical site. (K050807, in addition to the above, provides also illumination and aspiration functionalities).

The difference is that only our device and K113857 allow the tip to move, for the surgeon to select the desired angle. The other predicate devices have fixed tip. K113857 has a pre-curved Nitinol tube enclosed within the main (external) stainless steel shaft that projects out of the handle. As the Nitinol tube projects out of the main shaft, the fiber optic follows the curvature of the Nitinol tube. Our device, on the contrary, has a fixed and pre-curved PEEK tip, which changes angle, as a straightening (internal) stainless steel tube penetrates it internally. The fiber optic within the pre-curved tip follows the curvature of the pre-curved tip.

In terms of design, our device uses the same components as K021696 (and K050807, except for illumination and aspiration functions), but with two changes: (a) enhanced

fiber optic specifications, and (b) a movable tip that was tested to be substantially equivalent in its performance to K113857.

Material and chemical composition:

All predicate devices have the same component list as our device: glass fiber optic, plastic protective sheath that covers the fiber optic, metallic laser connector, plastic handle and stainless steel tip. In addition to the above, our device and K113857 have other materials, namely, PEEK tube for our device, and Nitinol tube for K113857.

Laser output properties for our device, K113857 and K021696 (and indirectly K050807, having the same fiber optic as K021696) were successfully tested. In other words, the intended functionality of our device was not affected by the change in materials.

Our device is sterile with sterility assurance level of SAL 10-6, as per documented evidence provided within the submission, by running an additional fractional cycle based on currently validated ethylene oxide sterilization cycle.

Energy used:

All predicate devices and our device do NOT emit energy, but only transmits laser energy from the connector side to the tip side.

The fiber optic of K021696 and K050807 was cleared originally for 514 to 532 nm, then subsequently for 500 to 1,100 nm.

K121187 was cleared for 500 to 900 nm.

Our device covers 500 to 1,100 nm, as for K021696 and K050807.

Our device, K113857 and K021696 (and indirectly K050807, having the same fiber optic as K021696) have been tested for up to 1,500 mW, with comparable and acceptable laser output characteristics.

Biocompatibility testing

The biocompatibility evaluation for Ophthalmed Bending Laser Probes (Models A207000, A807000, and A307000) was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO 10993, as recognized by FDA.

The battery of testing included the following tests:

- Cytotoxicity (L929 Neutral red uptake, 4 concentrations, as per ISO 10993-5:2009, GLP study)
- Irritation (intracutaneous injection, as per ISO 10993-10:2010, GLP study)
- Sensitization (Kligman maximization, as per ISO 10993-10:2010, GLP study)

The device is considered tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable

Software verification and validation testing

Not applicable

Mechanical and acoustic testing

Our device is substantially equivalent to K113857 and K021696 (and indirectly K050807, having the same fiber optic as K021696), as far as laser transmission, spot size, energy distribution and linearity, at baseline and after prolonged conditions.

Three 20g, three 23g and three 25g sterile probes were subjected to various tests, along with predicate devices, as described below, in accordance with 21 CFR 807.92(b)(1):

Laser transmission:

i- Ophthalmed probes as per K021696: 96 to 97%

ii- Synergetics probes as per K113857: 92 to 97%

iii- Probes under this submission K142830: 94 to 95%

The above transmission rates were substantially the same prior and after an abuse test based on 1,500 shots at 1,500mW, with pulse duration of 200 msec at 50 msec pulse intervals, with transmission rates measured at 1,000mW.

Spot size and energy distribution:

The same laser probes (K021696, K113857 and K142830) were also subjected to additional tests. Projecting the laser beam onto an appropriate surface, photos were taken at 1000mW, indicating no changes before and after the same abuse test of 1500mW, concerning the spot sizes and energy distribution.

The energy distribution was confirmed to be uniform for the three 510k submissions.

Also, the average divergence angle was determined to be 20 degrees for K113857, 14 degrees for K021696 and 16 degrees for K142830.

Linearity:

The laser probes of K113857 and K142830 were tested for linearity at 25%, 50%, 75% and 100% of knob sliding. Again, the same abuse test of 1500mW did not affect the results. It was determined that for sizes of 20g and 23g of K142830, the tip bends 20

deg, 37.5 deg, 45 deg and 55 deg, at 25%, 50%, 75% and 100% sliding, respectively, but 15 deg, 27.5 deg, 37.5 deg and 42.5 deg for 25g. In comparison, K113857 reflected 22.5 deg, 42.5 deg, 60 deg and 75 deg for 20g probe, but 20 deg, 30 deg, 40 deg, and 45 to 60 deg for 25g probe, respectively as well (at 25%, 50%, 75% and 100% of sliding).

Animal study

Not applicable.

Clinical studies

Not applicable.

VII. CONCLUSIONS

The various tests, internal and external, document that our device is substantially equivalent to the predicate device. Our laser output is similar, our mechanism is similar, our biocompatibility is tested, our sterility is documented, and our overall structure / components is similar.