DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 20, 2015

Emtron Elektronik Ve Mekanik
Sanayi Ve Ticaret Lim
Dr. Mehmet Melek
President
Bebek Yolu Sokagi 23/3 Etiler
Istanbul, 34337 TR

Re: K133019
Trade/Device Name: Fiberion Ophthalmic Endolaser Probe
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: January 9, 2015
Received: January 12, 2015

Dear Dr. Melek:

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 yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, MD
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 on last page.

510(k) Number *(if known)*
K133019

Device Name
Fiberion Ophthalmic Endolaser Probe

Indications for Use *(Describe)*

Fiberion Ophthalmic Endolaser Probes are intended for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye, the illumination function is indicated for use to illuminate the interior of the eye. The probes are offered with straight or angled tips, and with a series of connectors that allows them to be used with compatible laser systems. The probes are cleared for use for the particular indications of the laser system to which they are attached

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary
EMTRON™ Corporation
Fiberion™ Ophthalmic Endolaser Probes

Submitter's Name, Address, Telephone Number, E-mail, Contact Person and Date Prepared

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Dr. Mehmet Melek
Date Prepared: February 20, 2015

Device Information

Trade Name: Fiberion Ophthalmic Endolaser Probes
Classification Name: Laser, Ophthalmic, Accessory
CFR Section: 886.4390
Class II
Product Code: HQF

Predicate Devices

Fiberion Ophthalmic Endolaser Probes is substantially equivalent in intended use and/or method of operation to other currently legally marketed laser probes of IRIDEX Corporation's IRIS Medical EndoProbe (K022228).

Device Description

Fiberion endolaser probes are designed to be connected to ophthalmic laser photocoagulators and to transmit laser energy inside the patient's eye. One end of the probe contains a connector for attachment to the laser unit, the other, a tip section to be introduced inside the eye. Device components are an input connector, a glass fiber optic protected by a buffer coating, a protective tubing, an aluminum handle with a medical grade stainless steel needle. The illuminating endolaser probe has an additional illumination fiber optic.

List of Fiberion Ophthalmic Endolaser Probes

SMA-S	: Standard SMA connector, straight 0,9mm (20 Gauge) tip
SMA-A	: Standard SMA connector, angled 0,9mm (20 Gauge) tip
E-SMA-S	: Extended SMA connector, straight 0,9mm (20 Gauge) tip
E-SMA-A	: Extended SMA connector, angled 0,9mm (20 Gauge) tip
E-CYL-S	: Cylindrical connector, straight 0,9mm (20 Gauge) tip
E-CYL-A	: Cylindrical connector, angled 0,9mm (20 Gauge) tip
E-906-S	: Extended SMA 906 connector, straight 0,9mm (20 Gauge) tip
E-906-A	: Extended SMA 906 connector, angled 0,9mm (20 Gauge) tip
U-SMA-S	: SMA connector with long handle, straight 0,9mm (20Gauge) tip

U-SMA-A	: SMA connector with long handle, angled 0,9mm (20Gauge) tip
SMA-400-S	: Standard SMA connector, 400 micron fiber, straight 0,9mm (20Gauge) tip
SMA-400-A	: Standard SMA connector, 400 micron fiber, angled 0,9mm (20Gauge) tip
STA-S	: ST connector with long ferrule, straight 0,9mm (20 Gauge) tip
STA-A	: ST connector with long ferrule, angled 0,9mm (20 Gauge) tip
SMA-23-S	: Standard SMA connector, straight 0,6mm (23 Gauge) tip
SMA-23-A	: Standard SMA connector, angled 0,6mm (23 Gauge) tip
E-SMA-23-S	: Extended SMA connector, straight 0,6mm (23 Gauge) tip
E-SMA-23-A	: Extended SMA connector, angled 0,6mm (23 Gauge) tip
E-CYL-23-S	: Cylindrical connector, straight 0,6mm (23 Gauge) tip
E-906-23-S	: Extended SMA 906 connector, straight 0,6mm (23 Gauge) tip
E-906-23-A	: Extended SMA 906 connector, angled 0,6mm (23 Gauge) tip
U-SMA-23-S	: SMA connector with long handle, straight 0,6mm (23Gauge) tip
U-SMA-23-A	: SMA connector with long handle, angled 0,6mm (23Gauge) tip
SMA-400-23-S	: Standard SMA connector, 400 micron fiber,straight 0,6mm (23 Gauge) tip
STA-23-S	: ST connector with long ferrule, straight 0,6mm (23 Gauge) tip
STA-23-A	: ST connector with long ferrule, angled 0,6mm (23 Gauge) tip
SMA-25-S	: Standard SMA connector, straight 0,5mm (25 Gauge) tip
SMA-25-A	: Standard SMA connector, angled 0,5mm (25 Gauge) tip
E-SMA-25-S	: Extended SMA connector, straight 0,5mm (25 Gauge) tip
E-SMA-25-A	: Extended SMA connector, angled 0,5mm (25 Gauge) tip
E-906-25-S	: Extended SMA 906 connector, straight 0,5mm (25 Gauge) tip
E-906-25-A	: Extended SMA 906 connector, angled 0,5mm (25 Gauge) tip
U-SMA-25-S	: SMA connector with long handle, straight 0,5mm (25Gauge) tip
STA-25-S	: ST connector with long ferrule, straight 0,5mm (25 Gauge) tip
STA-25-A	: ST connector with long ferrule, angled 0,5mm (25 Gauge) tip
SMA-27-S	: Standard SMA connector, straight 0,4mm (27 Gauge) tip
E-SMA-27-S	: Extended SMA connector, straight 0,4mm (27 Gauge) tip
E-906-27-S	: Extended SMA 906 connector, straight 0,4mm (27 Gauge) tip
STA-27-S	: ST connector with long ferrule, straight 0,4mm (27 Gauge) tip
ILL-SMA-S	: Standard SMA connector, straight 0,9mm (20 Gauge) tip
ILL-SMA-A	: Standard SMA connector, angled 0,9mm (20 Gauge) tip
ILL-E-SMA-S	: Extended SMA connector, straight 0,9mm (20 Gauge)tip
ILL-E-SMA-A	: Extended SMA connector, angled 0,9mm (20 Gauge) tip
ILL-E-906-S	: Extended SMA 906 connector, straight 0,9mm (20Gauge) tip
ILL-E-906-A	: Extended SMA 906 connector, angled 0,9mm (20Gauge) tip
ILL-U-SMA-S	: SMA connector with long handle, straight 0,9mm (20Gauge) tip
ILL-U-SMA-A	: SMA connector with long handle, angled 0,9mm (20Gauge) tip
ILL-STA-S	: ST connector with long ferrule, straight 0,9mm (20 Gauge) tip
ILL-STA-A	: ST connector with long ferrule, angled 0,9mm (20 Gauge) tip

Intended Use

Fiberion Ophthalmic Endolaser Probes are intended for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye, the illumination function is indicated for use to illuminate the interior of the eye. The probes are offered with straight or angled tips, and with a series of connectors that allows them to be used with compatible laser systems. The probes are cleared for use for the particular indications of the laser system to which they are attached.

Substantial equivalence

Application for 510K	Substantial equivalence to
Fiberion Ophthalmic Endolaser Probes	IRIDEX Corporation's IRIS Medical EndoProbe (K022228)
Light transmission for photocoagulation	Light transmission for photocoagulation
Aluminum handpiece	Aluminum handpiece
Stainless steel needle	Stainless steel needle
Glass optical fiber	Glass optical fiber
Thermoplastic rubber jacket	Vinyl jacket
ETO sterilized.	ETO sterilized.

Differences between the Fiberion Ophthalmic Endolaser Probes and the predicate device

Some terminology differences exist in the intended use description due to trademark issues, but both devices' intended use is exactly the same.
Some models of the predicate device are not available in the Fiberion line.
Fiberion probes offer a range of connectors that have been validated with the ophthalmic lasers listed in the instructions for use. The probes have been used internationally for years without safety or laser compatibility problems.
The protective tubing which does not come in contact with the patient is of a different material. Fiberion probes use thermoplastic rubber meeting FDA food grade requirements.
Hence, none of these differences are cause for safety or effectiveness concerns.

Bench testing

Fiberion Ophthalmic Endolaser Probes and the predicate device were tested for laser power transmission, beam divergence, beam density homogeneity, and additionally for illuminating models, illumination intensity and illumination area diameter; and were found to be equivalent. Fiberion Ophthalmic Endolaser Probes were tested for safe delivery of the intended output power.

Laboratory testing

Fiberion Ophthalmic Endolaser Probes were tested for sterility and their sections in contact with the patient for biocompatibility, EO-ECH residues and endotoxins and were found to fulfil the requirements. EO levels were determined to be < 1.25 micrograms per device, ECH levels < 5 micrograms per device, and Endotoxin levels < 0.2 Endotoxin units per device.

Conclusion

Fiberion Ophthalmic Endolaser Probes shares similar indications for use, materials, and similar performance characteristics as, and thus are substantially equivalent to, IRIDEX Corporation's IRIS Medical EndoProbe (K022228).