April 20, 2018

InnovaQuartz LLC
Stephen Griffin
Chief Technology Officer
23030 North 15th Ave
Phoenix, Arizona 85027-1315

Re: K180140
Trade/Device Name: ProFlex® Laser Fibers
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: January 1, 2018
Received: January 18, 2018

Dear Stephen Griffin:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180140

Device Name
ProFlex® Laser Fibers

Indications for Use *(Describe)*
ProFlex® Laser Fibers are intended for use in laser-based surgical applications including, but not limited to endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision and of soft and cartilaginous tissues. While designed primarily for holmium (Ho:YAG) lasers, ProFlex laser fibers may be used with any laser wavelength between 500 nm and 2200 nm that have been cleared for surgical use including, but not limited to frequency doubled Nd:YAG (KTP) lasers, argon lasers, diode lasers, alexandrite lasers, ruby lasers, dye lasers, Nd:YAG lasers and Tm:YAG lasers.

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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623-434-1895
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510(k) Summary

Sponsor/Owner/Holder:

InnovaQuartz LLC
23030 N 15th Ave
Phoenix, AZ 85027-1315
623-434-1895

Contact:

Stephen Griffin, CTO
623-434-1895 (main) x101
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steveg@innovaquartz.com

Registration Number: 3010933841

Date: 4/19/2016

Subject Device Name:

Trade Name:	ProFlex® Laser Fibers
Common Name:	Laser Fiber
Classification:	Laser Instrument, Surgical, Powered Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation:	21 CFR §878.4810
Product Code:	GEX
Product Class:	II
Panel:	General and Plastic Surgery

Subject devices are substantially equivalent to the primary predicate devices.

Predicate Device(s):

Primary Predicate Device:

ProFlex® Laser Fibers (K142638)

Reference Predicate:

EndoBeam™ Holmium Laser Fibers (K120926)

Device Description:

Subject devices and primary predicate devices are fiber optic energy delivery devices consisting of a stainless steel laser connector, e.g. SMA 905, an anodized aluminum expansion nut, strain relief, doubly step index clad optical fiber (fluoroacrylate over fluorine doped fused silica) with an ethylene tetrafluorethylene (ETFE, Tefzel™) protective jacket and are available in five nominal fiber core diameters (200 µm, 273 µm, 365 µm, 550 µm, 910 µm, and 940 µm), three nominal lengths (3 meters, 3.5 meters and 4.25 meters) and two laser-formed working tips (flat and orb). Subject devices and primary predicate devices are equipped with spatial and angular laser launch overfill protection -- a protective and guiding quartz ferrule, fused about the fiber input face upon which an input lens is laser-formed for high laser and physical damage threshold and for collimation of the laser focus energy within the optical fiber – and ruggedized output tips designed for ease of transit in flexible ureteroscopes and stone basket channels. Smaller fibers (where base fiber cores are smaller than laser foci) are equipped with tapered inputs where larger fibers are straight terminations.

Subject devices are packaged in a coiled high density polyethylene (HDPE) tube carrier providing ease of dispensing within the surgical field while maintaining sterility. All materials of construction are USP Class VI biocompatible and are compatible with flash autoclave and ethylene oxide (EtO) sterilization.

Intended Use:

The intended use of the subject device is identical to the intended use of the primary predicate device.

“Proflex® Laser Fibers are intended for use in laser-based surgical applications including, but not limited to endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision and of soft and cartilaginous tissues. While designed primarily for holmium (Ho:YAG) lasers, ProFlex fibers may be used with any laser wavelength between 500nm and 2200nm that have been cleared for surgical use including, but not limited to frequency doubled Nd:YAG (KTP) lasers, argon lasers, diode lasers, alexandrite lasers, ruby lasers, dye lasers, Nd:YAG lasers and Tm:YAG lasers.”

Technological Characteristics:

Subject devices are provided in longer available lengths than the primary predicate devices to accommodate greater distances that must be traversed in modern laser surgery where laser ports on some lasers have been lowered, access to anatomical lumen may be less direct and endoscopic device working channels are longer.

Performance Testing (Bench and User Evaluation):

Subject and predicate fibers were laser power tested in relaxed and strained (bent) configurations using a cleared surgical holmium laser generator. Subject devices performed as well than the predicate devices in all cases. Accordingly, subject devices are determined to be as safe and as effective as the predicate devices.

The shelf life of the subject device is determined to be 2 years per accelerated aging tests.

Manufacturing, Packaging and Sterilization Facility:

Subject devices are designed, manufactured, packaging and sterilized within the InnovaQuartz manufacturing facility at Phoenix, Arizona. All manufacturing equipment has been validated as appropriate for the intended functions and sterilization is complaint with ISO 11135:2014 standards.

Conclusion:

A direct comparison of key characteristics demonstrates that subject device are substantially equivalent to the primary predicate device in terms of materials of construction, intended uses, technological considerations and performance characteristics. Subject devices are as safe, as effective and perform as well the predicate devices.