**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

December 19, 2014

InnovaQuartz LLC
Mr. Stephen Griffin
Vice President for Engineering, Research and Development
23030 North 15th Avenue
Phoenix, Arizona 85027

Re: K142638
Trade/Device Name: Proflex™ Laser Fibers (Proflex 200 and Proflex 273)
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: September 29, 2014
Received: October 1, 2014

Dear Mr. 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.

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,

Binita S. Ashar -S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K142638

Device Name

ProFlex™ Laser Fibers (ProFlex 200 and ProFlex 273)

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™ 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.

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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innovaquartz.com

# 510(k) Summary

**Sponsor/Owner/Holder:**

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

**Contact:**

Stephen Griffin
VP Engineering, R&D
623-434-1895 (main) x101
623-229-5174 mobile
steveg@innovaquartz.com

**Registration:**

At the time of this writing, the establishment registration fee has been paid

**Device Name:**

| | |
|---|---|
| Trade Name: | ProFlex™ Laser Fibers<br>ProFlex™ 200 (P/Ns: S-LLF200TL, R-LLF200TL)<br>ProFlex™ 273 (P/Ns: S-LLF273TL, R-LLF273TL) |
| Common Name: | Laser Instrument, Surgical, Powered |
| Classification: | Laser surgical instrument for use in general and plastic surgery and in dermatology (21CFR 878.4810, Product Code GEX, Class II) |
| Panel: | General and Plastic Surgery |

**Legally Marketed Predicate Device(s):**

| | |
|---|---|
| Trade Name: | Laser Peripherals Holmium Bare Fibers<br>Specifically model HB-200 |
| Common Name: | Laser Instrument, Surgical, Powered |
| Classification: | GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology – 21 CFR 878.4810, Class II |
| 510(k) Number: | K972272 issued to Laser Peripherals, Inc., 1000 Boone Ave. North, Suite 300, Golden Valley, MN |

**AND**

| | |
|---|---|
| Trade Name: | SureFlex™ and AccuFlex™ Laser Lithotripsy Fibers specifically model LLF200TG |
| Common Name: | Laser Instrument, Surgical, Powered |

| | |
|---|---|
| Classification: | GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology – 21 CFR 878.4810, Class II |
| 510(k) Number: | K050108 awarded to InnovaQuartz Incorporated, 23030 N 15th Ave, Phoenix, AZ 85027 and now held by AMS Innovation Center, 3070 Orchard Dr, San Jose, CA 95134 |

**Device Description:**

The ProFlex™ Laser Fibers 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 two fiber core diameters: 200µm & 273µm. The ProFlex™ Laser Fibers are equipped with laser launch overfill protection (spatial and angular) -- a protective, transmissive quartz ferrule, fused about the fiber input face and laser polished for high damage threshold (laser and physical), and ruggedized output tips designed for ease of transit in flexible ureteroscopes. All materials of construction are USP Class VI biocompatible and compatible with flash autoclave and EtO sterilization.

**Intended Use:**

Proflex™ Laser Fibers have the same indications for use as the predicate SureFlex™ and AccuFlex™ Laser Lithotripsy Fibers:

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.

Differences in the indications for use between ProFlex™ and the Laser Peripherals Holmium Bare Fibers predicate are limited to the range of laser wavelengths for which compatibility is identified. Laser Peripherals

lists the two most common wavelengths for which low [OH] fused silica core optical fiber is used in surgical applications while ProFlex™, SureFlex™ and AccuFlex™ specify the spectral region of compatibility and offer examples of surgical lasers operating within this range including, but not limited to, the two lasers identified in the Laser Peripherals predicate device indications for use.

**Technological Characteristics:**

The ProFlex™ line of fiber optic energy delivery devices is similar to Laser Peripherals Holmium Bare Fibers in materials of construction and indications for use and is identical to the SureFlex™ and AccuFlex™ predicate devices in materials, methods of construction, indications for use and minimum performance criteria.

The principal differentiating characteristics of ProFlex™ versus the Laser Peripherals predicate device lie in the techniques employed for tolerance of fiber core overfill and in output tip formation. Laser Peripherals exploits the standard “fiber well” termination, also known as “high power” terminations in the art, where the connector face is counter-bored for a depth of millimeters to remove adhesive and connector materials from the focal plane and immediate vicinity of the laser focal spot. ProFlex™ utilizes a transparent (transmissive) fused quartz ferrule, positioned about the fiber diameter at the proximal terminus and fused to the fiber to space the fiber core apart from adhesive or connector materials at the focal plane.

ProFlex™ (like SureFlex™ and AccuFlex™) presents a laser polished input face to the laser aperture for a maximum damage threshold surface (physical and mechanical) that is easily cleaned, versus the Laser Peripherals exposed, thin and mechanically polished, flat fiber face. Fibers with core diameters that are on the order of, or smaller than, the laser focal spot diameter are up-tapered for ProFlex™ and the SureFlex/AccuFlex predicate devices such that the fiber core presented to the laser focus is as large or larger than the laser focal spot diameter. Rather than spilling spatial overfill energy onto the fiber connector or reflecting the energy back into the laser aperture, ProFlex™ (like the SureFlex(/AccuFlex predicate) captures spatial overfill and delivers the energy into the fiber optic conduit.

The differences between these two fiber designs are: the fiber taper ratio (input core diameter), the length of the transmissive ferrule and the

position of the brass crimp at the distal terminus of the transmissive ferrule. These design differences result for over a decade of experience with the true optical characteristics of approved surgical laser foci and improved assembly strategies for higher concentricity of the fiber within the connector body that, combined, permit the use of smaller taper ratios.

Laser Peripherals employs a mechanical polish for the output tip that is produced on a stripped (ETFE) section of approximately 5mm to 8mm long where ProFlex™ utilizes a laser to vaporize and melt the output tip into a small, slightly convex and aspheric output on a section of stripped of ETFE 3mm to 4mm long. The sharp, 90 degree edge of the mechanically polished fiber tip (for the predicate LP device) is known to scratch and dig into flexible ureteroscope liners, causing damage and/or hanging up and snapping off. ProFlex™ Laser Fiber tips have rounded edges so that there is no sharp edge to scratch or dig into the soft ureteroscope liner and the shorter exposed fiber length reduces the risk of tip detachment.

**Substantial Equivalence:**

A direct comparison of key characteristics demonstrates that ProFlex laser fibers are substantially equivalent to both predicate devices in terms of materials of construction, intended uses, technological considerations and performance characteristics. ProFlex™ Laser Fibers are as safe, as effective and perform as well as the predicate devices.

The performance of ProFlex™ 200 fibers were compared to SureFlex™ LLF200TG for the 200µm core fiber design because, to our knowledge, SureFlex™ LLF200TG is the only true 200µm core fiber available on the market. The ProFlex 273 fibers were compared to Laser Peripherals HB200 because it is a readily available fiber, commonly used within the intended market and the Laser Peripherals' HB200 – identified as "Holmium Laser Fiber 200 micron" on the label -- is actually a 273µm core fiber where the fiber raw material is substantially equivalent to the ProFlex™ 273 base fiber material to which it is rationally compared. ProFlex's technology is also fairly well bracketed between the two chosen predicate devices.

**Performance Testing (Bench and User Evaluation):**

Briefly, subject and predicate fibers were power tested in relaxed and strained (bending) configurations using a cleared surgical holmium laser. ProFlex™ Laser Fibers performed better than the predicate devices in all

four cases -- 200µm core ProFlex™ versus 200µm core SureFlex™, relaxed and stressed, and 273µm core ProFlex™ versus 273µm core Laser Peripherals, relaxed and stressed – individually, on average and in consistency. Accordingly, ProFlex™ fibers are determined to be as safe and as effective as the predicate devices. ProFlex has also been evaluated by one OEM holmium laser manufacturer and found to preform well.

**Manufacturing, Packaging and Sterilization Facility:**

Proflex™ Laser Fibers are designed, manufactured, packaging and sterilized within the same facility, the same model EtO sterilizer and with the same personnel that originally produced the SureFlex™ and AccuFlex™ Laser Fiber predicate devices, and their predecessors through 2008. While the manufacturing equipment is mostly new, it is substantially equivalent to the equipment used to make the predicate SureFlex™ and AccuFlex™ Laser Fibers, is validated to perform the processes for which they are intended.