September 20, 2021

InnovaQuartz LLC
Stephen Griffin
Chief Technology Officer
23030 N. 15th Ave
Phoenix, Arizona 85027

Re: K203799
Trade/Device Name: ProFlex CO2 Laser Fiber (Model: S-COF500)
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: August 18, 2021
Received: August 20, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva U. Pandya -S

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203799

Device Name
ProFlex CO2 Laser Fiber (Model: S-COF500)

Indications for Use *(Describe)*
ProFlex CO2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K203799

1. Date of Preparation
   09/17/2021

2. Applicant

Name:	InnovaQuartz, LLC.
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Registration #:	3010933841
Contact Person:	Stephen Griffin, CTO
Telephone:	623-434-1895 (main) x101, 623-229-5174 (mobile)
Email:	steveg@innovaquartz.com

3. Identification of the Proposed Device

Trade Name:	ProFlex CO_2 Laser Fiber
Common Name:	Laser Fiber
Model(s):	S-COF500
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	II
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Review Panel:	General & Plastic Surgery

4. Identification of Predicate Device

510(k) Number:	K100384
Product Name:	CO2 Laser WaveGuide
Manufacturer:	Lumenis Ltd., 13 Hayetzira St. (POB 240), Yokneam Industrial Park, Yokneam, 20692 Israel

5. Device Description

ProFlex CO_2 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, a hollow glass tube having a dielectric coating (silver/silver iodide) in the bore and a fluoropolymer outer coating and an ethylene tetrafluoroethylene copolymer (ETFE, Tefzel™) protective jacket.

ProFlex CO_2 Laser Fibers are packaged in a coiled and tubular, high-density polyethylene (HDPE) carrier providing improved ease of dispensing within the surgical field while maintaining sterility. Coils are contained within non-woven/impermeable polymer, e.g. Tyvek/Mylar, sterile pouches, validated for three-year shelf life, and protected with an outer, nonsterile fiberboard carton. Both sterile pouch and carton are labeled.

All ProFlex CO_2 Laser Fiber materials of construction are USP Class VI biocompatible and are compatible with ethylene oxide (EtO) sterilization.

ProFlex CO_2 Laser Fibers are for prescription use only.

6. Indications for Use

ProFlex CO_2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures.

7. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

ITEM	Proposed Device	Predicate Device K161926	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
Intended Use	ProFlex CO_2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures.	The fiberlase CO2 laser waveguide is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The fiberlase CO2 laser waveguide is indicated for use in open surgical procedures such as ent surgery and laparoscopy and endoscopic procedures. The device is limited to carbon dioxide lasers having a sma-905 connector.	SE

The technical characteristics of the subject and predicate devices are compared in the table below.

Device & Predicate Device(s):	K203799 (Subject Device)	K100384 (Primary Predicate)
General Device Characteristics		
Laser Type and wavelength (nm)	CO2, 10600	CO2, 10600
Inner diameter (µm)	500	500
Outer diameter (µm)	1040	1040
Length (m)	2	2
Maximum Input Power (W, CW)	40	40
Maximum Input Power (W, super-pulse mode)	15	15
Operative Bending	40mm radius @ 45^0, 40 W 40mm radius @ 90^0, 30 W	40mm radius @ 45^0, 40 W 40mm radius @ 90^0, 30 W
Transmission Efficiency (Loss)	≥ 60% (< 40%)	> 60 % (< 40 %)

The materials used in the construction of the subject and predicate devices are compared below.

Description: Component	**Subject Device: ProFlex CO_2 Laser Fiber**	**Predicate Device: FiberLase CO_2 Laser WaveGuide K100384**
Package	HDPE tube with clips	Paper Card
X-Nut	Blue anodized aluminum	Nylon
Capillary cladding	Fluoropolymer	Fluoropolymer
Capillary buffer	Clear ETFE	Clear ETFE
Capillary base	Fused silica	Fused silica
Dielectric coating	Silver/Silver Iodide	Silver/Silver Iodide
Laser connector	Stainless Steel 905 SMA	Stainless Steel 905 SMA
Strain Relief	Black Santoprene rubber boot	Rubber boot
Proximal Cap	White Santoprene vented cap	Vented dust cap
Distal Cap	Silicone cap	Silicone cap
Bend Limiter	Polyolefin heat shrink	Heat shrink
Capillary Adhesive	USP VI Epoxy	Epoxy
Sterile package	Tyvek/Mylar film chevron pouch	Tyvek/Mylar film chevron pouch

8. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- Bench Testing to support labeling and verify the performance (e.g., ProFlex CO_2 Laser Fiber Instructions for use and labels, Fiber Design Verification, Packaging Design Verification)
- Performance Qualification of ProFlex CO_2 with Hoop Insert Packaging to Demonstrate 10^{-6} Sterility per ISO 11135:2014 and Ethylene Oxide sterilization residuals per ISO 10993-7:2008

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.