February 19, 2025

Quanta System SpA
Dario Bandiera
Regulatory Affairs Manager
Via Acquedotto 109
Samarate, VA 21017
Italy

Re: K243588
Trade/Device Name: Single Use CO2 Laser Fiber (HAF005001)
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: November 6, 2024
Received: November 20, 2024

Dear Dario Bandiera:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.19 14:10:59 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243588

Device Name
Single Use CO2 Laser Fiber (HAF005001)

Indications for Use *(Describe)*
Single Use CO2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures. Indications involving heart or central circulatory system, or the central nervous system are excluded from optical fibers intended use.

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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K243588 - 510(k) Summary

Applicant / manufacturer:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	6th November 2024
Model name:	Single Use CO2 Laser Fiber (HAF005001)
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Predicate device	ProFlex CO2 Laser Fiber (K203799) manufactured by InnovaQuartz LCC.

1 Abbreviations

ETFE= Ethylene tetrafluoroethylene
EtO= Ethylene oxide

2 Device description

Single Use CO2 laser fiber is a single use hollow fiber compatible to CO_2 laser systems with the following specifications:

- equipped with F-SMA receptacle connector;
- equipped with a CO_2 laser source, emitting radiation at 10.6 µm wavelength with pulsed and continuous wave (CW) emission mode;
- able to produce a beam of maximum 300 µm diameter with maximum 30 mrad divergence at the fiber input plane;
- with a maximum power of 40 W;
- equipped with an internal compressed air delivery system capable to generate a positive air flow inside the fiber tube;

The main technical specifications are reported in Table 1.

Table 1: Fiber main specifications. $D_{1\text{-}3}$ are reported in Figure 1.

D_1 (µm)	500
D_2 (µm)	650
D_3 (µm)	1040
Numerical aperture	0.04
Fiber length (m)	2
Connector	SMA905
Tip length (mm)	3
Number of uses	1
Sterilization method	EtO
Shelf life	5 years
Power transmission	60-70%
Short term minimum bending radius	4 cm at 120°
Packaging	Double pouch

The fiber structure is reported in Figure 1. It is composed of two layers: a capillary tube made of fused silica and a jacket made of ETFE. The cavity is covered by two films: the outer one is made of silver and the inner one is made of silver iodide. Silver, due to its high reflectivity, allows laser beam reflection and, thus, propagation inside the cavity. The addition of a silver iodide film prevents silver film from oxidation. A summary of fiber materials is reported in Table 2. Such materials represent patient contacting materials.
D_1, the lumen diameter, also corresponds to the laser beam diameter.

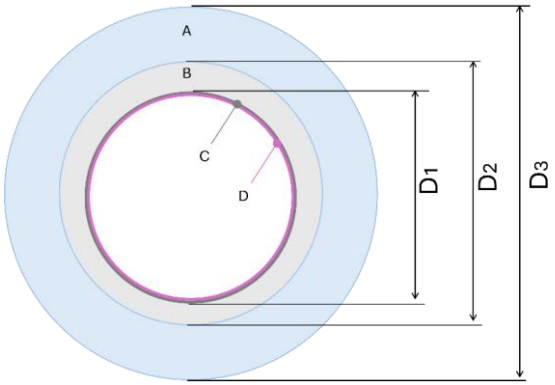

Figure 1: Optical fiber section. D_{1-3} are the diameters of the different layers. A, B, C, D represent the different layers whose materials are reported in Table 2.

Table 2: Fiber materials.

	Layer	**Material**
A	Jacket	ETFE (*Tefzel*)
B	Capillary tube	Fused Silica
C	Outer coating	Silver
D	Inner coating	Silver iodide

Optical fiber main components are shown in Figure 2. It is equipped with a SMA905 connector to be coupled to the laser system and a code plug that, for laser systems equipped with a code plug connector, allows the laser device to detect the fiber presence. A protective cap, to be removed before use, is placed on the fiber tip. Strain relief protects the fiber from mechanical stress at the connector side.

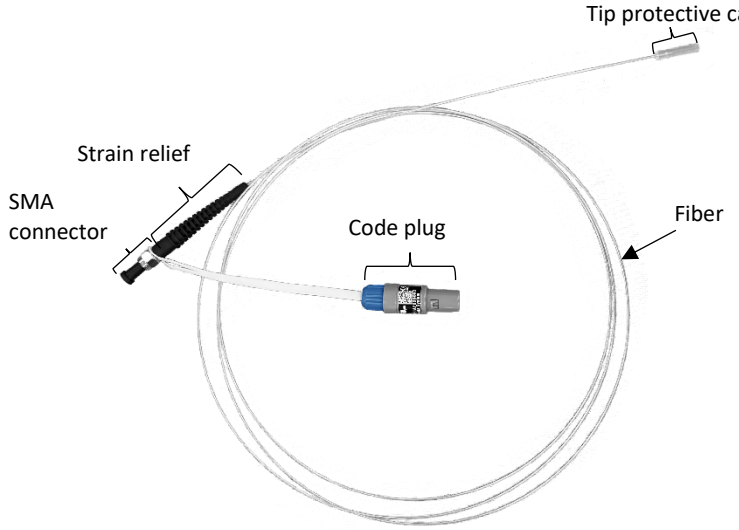

Figure 2: Fiber main components.

This kind of fiber needs to be connected to a laser system with an internal compressed air system. An air flow inside the fiber lumen is necessary to both cool the fiber and keep it free from debris.

3 Indication for use

Single Use CO2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures.
Indications involving heart or central circulatory system, or the central nervous system are excluded from optical fibers intended use.

4 Comparison with predicate

In Table 3 the main specifications of the subject device are summarized and compared to the predicate device. *ProFlex CO2 Laser Fiber* (InnovaQuartz LCC) has been selected as predicate device.

Table 3: Substantial equivalence comparison table.

	Subject device	**Predicate device**	**Equivalence rationale**
Model n°	*Single Use CO2 laser fiber*	*ProFlex CO2 Laser Fiber*	-
K number	-	K203799	-
Product code	GEX		
Indications for use	Single Use CO2 Laser Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures. Indications involving heart or central circulatory system, or the central nervous system are excluded from optical fibers intended use.	*ProFlex CO2 Laser* Fiber is indicated for the ablation, coagulation, excision, incision, and vaporization of soft tissue in open, endoscopic, and laparoscopic surgical procedures.	Same general indications (i.e. ablation, coagulation etc.) with the difference that we have excluded heart, central circulatory system and central nervous system from the intended use as, according to EU regulation 2017/745, a contact to these tissues would affect device risk classification (class III instead of IIa). The device keeps the same labelling and instructions for use for both US and EU (CE mark).
Compatible laser wavelength (µm)	10.6 (CO_2)	10.6 (CO_2)	The same
Maximum input power (W)	40	40	The same. Maximum input power has been verified with performance test report BRE20240109RD attached in e-star section "Performance testing".
Power transmission (%)	60-70	≥60%	The minimum transmission power is the same. Transmission has been characterized in performance report BRE20240109RD attached in e-star section "Performance testing".
Bending radius	4 cm at 120°	With power 0-30 W: 4 cm @90° With power 30-40W: 4 cm @45°	Similar. Verified in performance report BRE20240109RD attached in e-star section "Performance testing".
Lumen diameter D_1 (µm)	500	500	The same
Outer diameter D_3 (µm)	1040	1040	The same
Fiber length (m)	2	2	The same
Materials	A: ETFE (*Tefzel*) B: Fused silica C: Silver D: Silver iodide	A: ETFE (*Tefzel*) X: Fluoropolymer B: Fused silica C: Silver	The predicate device has an additional layer (fluoropolymer cladding).

	Subject device	Predicate device	Equivalence rationale
Model n°	*Single Use CO2 laser fiber*	*ProFlex CO2 Laser Fiber*	-
K number	-	K203799	-
		D: Silver iodide	Cladding usually has the only function to enhance fiber mechanical properties. The absence of this layer in the subject device doesn't affect safety and performance.
Connector type	SMA905	Stainless steel connector (e.g. SMA905)	The same
Number of uses	1	1	The same
Packaging	Polypropylene holder Double pouch made of: - Plastic film (PET/PP) - Medical grade paper	HDPE tubular carrier Pouch made of non-woven/impermeable polymer (e.g. Tyvek/Mylar)	Packaging has been validated for a 5 years shelf life after accelerated ageing (see e-star section "Reprocessing, Sterility, and Shelf-Life").
Sterilization method	EtO	EtO	The same
Shelf life	5 years	3 years	Shelf life has been validated by accelerated ageing on fiber packaging (see e-star section "Reprocessing, Sterility, and Shelf-Life")

5 Non-clinical tests

The present device was subject to non-clinical bench testing according to the following standards:

Table 4: Non-clinical tests summary.

Standard	Discussion	e-star section
ISO 10993-1: 2018 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process.	The following tests have been performed with positive results: - Cytotoxicity - Sensitization - Irritation - Acute systemic toxicity - Pyrogenicity	Refer to e-star section "Biocompatibility".
ISO 11607-1: 2019 Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Device packaging has been assessed after accelerated ageing (to simulate 5 years shelf life).	Refer to e-star section "Reprocessing, Sterility, and Shelf-Life".
ISO 11607-2: 2019 Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes		
ISO 11135: 2014 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	EtO sterilization validation has been performed for both sterilization sites (Steril Verona and Steris).	Refer to e-star section "Reprocessing, Sterility, and Shelf-Life".
Performance (laser transmission and minimum bending radius)	It has been verified that laser transmission is within 60 and 70% in both normal conditions and with the fiber bent at the minimum bending radius at both 25 and 40W.	Refer to e-star section "Performance testing".

The results of the non-clinical performance standards testing support that the subject device can be used safely and effectively.

6 Substantial equivalence discussion

Single Use CO2 laser fiber has comparable indications for use of the predicate device and equivalent technological characteristics as shown in Table 3. Moreover, non-clinical tests conducted (Table 4) support that the device can be used safely and effectively.

7 Conclusions

Based on the comparison and the non-clinical tests, the subject device is substantially equivalent to the predicate device.