February 26, 2021

Realton (Suzhou) Medical Technology Co., Ltd.
℅ Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street,
Panyu District
Guangzhou, Guangdong 510006
China

Re: K202702
Trade/Device Name: FLARE Single-Use Surgical Laser Fiber
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 22, 2021
Received: January 25, 2021

Dear Olivia Meng:

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 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)*
K202702

Device Name
FLARETM single-use surgical laser fiber

Indications for Use *(Describe)*
FLARETM single-use surgical laser fiber is intended to be used to deliver the laser radiation to the target tissue when used with compatible surgical lasers with operational wavelength between 532 nm- 2140 nm and equipped with SMA 905 compatible connector.
FLARETM single-use surgical laser fiber is indicated for use in general surgical applications for open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

Realton (Suzhou) Medical Technology Co., Ltd.
601 Room, B8 Building, 218 Xinghu Road, Suzhou Industrial Park, Suzhou, P.R.China
Phone: +86-512-62868599

Primary Contact Person:	Olivia Meng Regulatory Affairs Manager Guangzhou Osmunda Medical Device Technical Service Co., Ltd. Tel: (+86)-20-6231 6262 Fax: (+86) -20-8633 0253
Secondary Contact Person:	Mingzhu Liu Quality Manager Realton (Suzhou) Medical Technology Co., Ltd. Tel: (+86)-512-62868599
Date prepared	February 24, 2021

2. DEVICE

Device Name:	FLARE™ single-use surgical laser fiber
Common/Usual Name:	FLARE™ single-use surgical laser fiber
Model:	RLT105L1, RLT200L1, RLT272L1, RLT365-550L1, RLT365-730L1, RLT550L1, RLT600L1, RLT760L1, RLT940L1, RLT105S1, RLT200S1, RLT272S1, RLT365-550S1, RLT365-730S1, RLT550S1, RLT600S1, RLT760S1, RLT940S1
Regulation number	21 CFR 878.4810
Regulation Class:	II
Product Code:	GEX Powered Laser Surgical Instrument

3. PREDICATE DEVICE

SlimLine™ Family of Delivery Fibers, K170121

4. DEVICE DESCRIPTION

FLARE™ single-use surgical laser fiber is designed, manufactured by Realton (Suzhou) Medical Technology Co., Ltd.. The optical fiber material is fused quartz. One end of the fiber is connected to the medical laser equipment through a connector, and the other end directly outputs laser energy for laser operation. The product is sterilized by EO. It is a disposable medical device.

5. INDICATIONS FOR USE

FLARE™ single-use surgical laser fiber is intended to be used to deliver the laser radiation to the target tissue when used with compatible surgical lasers with operational wavelength between 532 nm- 2140 nm and equipped with SMA 905 compatible connector.

FLARE™ single-use surgical laser fiber is indicated for use in general surgical applications for open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	**Subject device**	**Predicate device**	**Discussion of difference**
Trade name	FLARE™ single-use surgical laser fiber	Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories (VersaPulse PowerSuite, Lumenis Pulse 30H, Lumenis Pulse 50H, Lumenis Pulse 60H, Lumenis Pulse 100H and Lumenis Pulse 120H)	NA
Device name	FLARE™ single-use surgical laser fiber	SlimLine™ Family of Delivery Fibers	NA
Manufacturer	Realton (Suzhou) Medical Technology Co., Ltd.	Lumenis Ltd.	NA
510 (k) number	K202702	K170121	NA
Product code	GEX	GEX	Same
Intended use	FLARE™ single-use surgical laser fiber is intended to be used to deliver the laser radiation to the target tissue when used with compatible surgical lasers with operational wavelength between 532 nm-2140 nm and equipped with SMA 905 compatible	Lumenis SlimLine fiber are intended for use with compatible lasers in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy.	Similar

	connector. FLARE™ single-use surgical laser fiber is indicated for use in general surgical applications for open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy.		
Contraindica-tions	Refer to the laser operator's manual for contraindications that may be specific to each specialty.	Refer to the laser operator's manual for contraindications that may be specific to each specialty.	Same
Prescription or OTC	Prescription	Prescription	Same
Components	The device is mainly composed of connector and bare fiber. Protective sleeve is around the bare fiber.	The fiber consists of a laser connector and a glass fiber.	Similar
Material of fiber	Fused quartz	Fused quartz	Same
Fiber core diameter (μm)	105, 200, 272, 365, 550, 600, 760, 940	272, 365, 550, 940	Similar
Fiber outer diameter (mm)	0.25, 0.40, 0.42, 0.55, 0.73, 0.75, 1.10, 1.40	0.45, 0.58, 0.78, 1.45	Similar
Fiber length	250 cm, 300 cm	250 cm, 310 cm, 450 cm	Similar
Applicable wave lengths	532nm~2140nm	532nm~2140nm	Same
Maximum transmission power	20 W, 100W, 120 W	15W, 45W, 120W	Similar
Minimum bending working radius (mm)	12, 20, 24	12, 14, 20, 24	Similar
Connector	SMA-905 standard optical connector	Secure identification system	Different
Laser systems compatibility	Applied to lasers with wavelengths from 532 nm to 2140 nm.	VersaPulse™ PowerSuite™ Single Wavelength Horimium VersaPulse PowerSuite Dual Wavelength VersaPulse P20 Lumenis Pulse™ 120H	Different
Sterilization	Ethylene oxide	Ethylene oxide	Same

The subject device and the predicate device are similar in some technical specification

including fiber core diameter, fiber outer diameter, fiber length, maximum transmission power, minimum bending working radius. The subject device is different from the predicate in the connector and laser system compatibility. However, these differences do not raise different questions of safety and effectiveness. The technological differences can be evaluated through the performance testing provided.

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for FLARE™ single-use surgical laser fiber was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Intracutaneous reactivity - (ISO 10993-10:2010)
- Systemic toxicity – (ISO 10993-11:2017)
- Hemocompatibility – (ASTM F756-17)

Performance testing

Performance testing was conducted on FLARE™ single-use surgical laser fiber. Technical parameters about dimension, optical performance and mechanical strength were evaluated in the performance testing. In addition, the shelf life was evaluated. All of the tested parameters met the predefined acceptance criteria.

8. CONCLUSION

The subject device has the same intended use as the laser fibers of the predicate device. The differences between the subject device and the laser fibers of the predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that FLARE™ single-use surgical laser fiber should perform as intended in the specified application conditions.

From the results of non-clinical data including the performance testing described, Realton (Suzhou) concludes that FLARE™ single-use surgical laser fiber is as safe and as effective as the laser fibers of the predicate device.