December 15, 2020

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: K202601
Trade/Device Name: Single-use sterile medical 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: November 26, 2020
Received: November 30, 2020

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)*
K202601

Device Name
Single-use sterile medical laser fiber

Indications for Use *(Describe)*
The device is a fiber optic delivery device intended for use with the laser system for its FDA cleared indications for use. The product can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.
The product will deliver 532 nm laser energy from a compatible laser console (Surgical Green Laser System) to tissue during surgical procedures, including photo-selective vaporization of the prostate for benign prostatic hyperplasia (BPH).

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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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.
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Phone: +86-512-62868599

Primary Contact Person:	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, CHN 510006 Guangdong 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	December 11, 2020

2. DEVICE

Device Name:	Single-use sterile medical laser fiber
Common/Usual Name:	Single-use sterile medical laser fiber
Model:	W760SF-30, B760SF-30, G760SF-30,P760SF-30, W760F-30, B760FF-30, G760FF-30 and P760FF-30
Regulation number	21 CFR 878.4810
Regulation Class:	II
Product Code:	GEX (Powered Laser Surgical Instrument)
Regulation Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and In Dermatology

3. PREDICATE DEVICE

K120870 GreenLight MoXyTM Fiber Optic

4. DEVICE DESCRIPTION

The single-use sterile medical laser fiber is designed, manufactured by Realton (Suzhou) Medical Technology Co., Ltd.. The product can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. The optical fiber material is fused quartz, and its core diameter is 760 μm. One end of the optical fiber is a special connector, which can be connected to the medical laser surgery system. The output structure of the other end of the optical fiber can be divided into side-firing type and front-firing type: W760SF-30, B760SF-30, G760SF-30 and P760SF-30 are side-firing types, W760F-30, B760FF-30, G760FF-30 and P760FF-30 are front-firing types.

The product is sterilized by EO. It is a disposable medical device.

The specification of the single- use sterile medical laser fiber is as followed:

Item	Specification
Overall Length	300 cm
Core Diameter	0.76 mm
Applicable wave lengths	532 nm
Minimum transmission efficiency	80 %
Maximum transmission power	180 W
Tensile strength	10 N
Minimum bending working radius	500 mm
Light output angle (side-firing types)	70°± 20°
Connector	SMA-905

5. INDICATIONS FOR USE

The device is a fiber optic delivery device intended for use with the laser system for its FDA cleared indications for use.

The product can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

The product will deliver 532 nm laser energy from a compatible laser console (Surgical Green Laser System) to tissue during surgical procedures, including photo-selective vaporization of the prostate for benign prostatic hyperplasia (BPH).

The indications for use statement for the subject device is same as the predicate device.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	Subject device	Predicate device	Discussion of difference
Device name	Single-use Sterile Medical Laser Fiber	GreenLight MoXy™ Fiber Optic	NA
Manufacturer	Realton (Suzhou) Medical Technology Co., Ltd.	American Medical Systems	NA
510 (k) number	NA	K120870	NA
Product code	GEX	GEX	Same
Intended use	The device is a fiber optic delivery device intended for use with the laser system for its FDA cleared indications for use. The product can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The product will deliver 532 nm laser energy from a compatible laser console (Surgical Green Laser System) to tissue during surgical procedures, including photo-selective vaporization of the prostate for benign prostatic hyperplasia (BPH).	Model Number 0010-2400 is a fiber optic delivery device intended for use with the GreenLight™ XPS Laser System for its FDA cleared indications for use. The Model Number 0010-2400 features a side firing mechanism delivering up to 180W of 532nm light to tissue. Model Number 0010-2400 can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Model Number 0010-2400 will deliver 532 nm laser energy from a compatible laser console (GreenLight™ XPS Laser System) to tissue during surgical procedures, including photoselective vaporization of the prostate for benign prostatic hyperplasia (BPH).	Same
Contraindica-tions	The fiber is contraindicated in the presence of severe urethral strictures; however, the system can be used in the treatment of urethral strictures with proper cautions. A severe stricture is any stricture with visible narrowing via urethrography or ultrasonography, with near total obstruction that make passage of instruments difficult or dangerous.	The fiber is contraindicated in the presence of severe urethral strictures; however, the system can be used in the treatment of urethral strictures with proper cautions. A severe stricture is any stricture with visible narrowing via urethrography or ultrasonography, with near total obstruction that make passage of instruments difficult or dangerous.	Same
Prescription or OTC	Prescription	Prescription	Same
Components	The device is mainly composed of four parts: fiber connect part (cap for connector, connector), fiber transmission part, fiber handle and treatment part (Side-firing type: bare fiber, laser firing point, laser firing	The device is mainly composed of metal cap, laser firing point, outer flow tubing, control knob, fiber handle, inlet flow tubing and connector, etc.	Similar

	indicator and fiber cap; front-firing type: bare fiber and laser firing point).		
Type	Front-firing and side-firing	Side-firing	Similar
Material of fiber	Fused quartz	Fused quartz	Same
Fiber core size	0.76 mm	0.75 mm	Similar
Catheter length	300 cm	305 cm	Similar
Operation length	34.5 cm	36 cm	Similar
Power density at 2 mm	@180W=326 W/mm^2 @120W=218 W/mm^2	@180W=326 W/mm^2 @120W=218 W/mm^2	Same
Applicable wave lengths	532 nm	532nm	Same
Maximum transmission power	180 W	180 W	Same
Total amount of energy transferred	643 KJ	643 KJ	Same
Connector	SMA-905 standard optical connector	Optical Connector	Different
Laser systems compatibility	Surgical Green Laser System	GreenLight^{TM} XPS Laser System	Different
Endoscope/Cystoscope compatibility	24 Fr continuous flow	22 to 24 Fr continuous flow	Similar
Sterilization	Ethylene oxide	Ethylene oxide	Same

The indications for use and technological characteristics of the subject and predicate devices are comparable. The subject device and the predicate device differ in some technical specifications such as components, connector and compatible laser systems. However, these differences do not raise different questions of safety and effectiveness.

7. SUMMARY OF NON-CLINICAL TESTING

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

Biocompatibility testing

The biocompatibility evaluation for single-use sterile medical 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
- Sensitization
- Irritation
- Systemic toxicity

Performance testing

Performance testing was conducted on single-use sterile medical 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 indications for use statement for the subject device is the same as that of the predicate. The differences between the subject device and its predicate device do not raise different questions of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that single-use sterile medical 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 the subject device single-use sterile medical laser fiber is substantially equivalent to the predicate device.