June 4, 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: K202828
Trade/Device Name: Surgical Green Laser System
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Laser Surgical Instrument for Use In General and Plastic Surgery and In Dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 25, 2021
Received: April 30, 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,

Mark J. Antonino, M.S.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K202828

Device Name
Surgical Green Laser System

Indications for Use *(Describe)*
The surgical green laser system is intended for surgical treatment of benign prostatic hyperplasia (BPH) through photo-selective vaporization of the prostate (PVP).

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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"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.
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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	May 31, 2021

2. DEVICE

Device Name:	Surgical Green Laser System
Common/Usual Name:	Surgical Green Laser System
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Model:	PVP-120, PVP-140, PVP-160, PVP-180
Regulation number:	21 CFR 878.4810
Regulation Class:	II
Product Code:	GEX Powered Laser Surgical Instrument

3. PREDICATE DEVICE

GreenLight XPS Laser System (K092735)

4. DEVICE DESCRIPTION

The surgical green laser system is designed, manufactured by Realton (Suzhou) Medical Technology Co., Ltd.. The device is a semiconductor pumped, Q-switched and double-frequency solid-state Nd:YAG green laser. The device has the following models according to different output laser powers: PVP-120, PVP-140, PVP-160 and PVP-180. It shall be used with the laser fibers cleared under K202601.

The pulse rate of the device is 10kH-18kH, and pulse width of the device is 100ns-180ns.

5. INDICATIONS FOR USE

The surgical green laser system is intended for surgical treatment of benign prostatic hyperplasia (BPH) through photo-selective vaporization of the prostate (PVP).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject device	Predicate device	Discussion of difference
Device name	Surgical green laser system	GreenLight XPS Laser System	NA
K number	K202828	K092735	NA
Manufacturer	Realton (Suzhou) Medical Technology Co., Ltd.	American Medical Systems, Inc.	NA
Indications for Use	The surgical green laser system is intended for surgical treatment of benign prostatic hyperplasia (BPH) through photo-selective vaporization of the prostate (PVP).	The GreenLight TM XPS Laser System is intended 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. Suggested applications include: General Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries. Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer,	Similar

		colitis, hemorrhoids). Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids. Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis. Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type. Ophthalmology: Post-vitrectomy endophotocoagulation of the retina. Plastic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures. Spinal Surgery: Percutaneous lumbar diskectomy. Thoracic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures. Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate	

		hyperplasia/hypoplasia (BPH).	
Contraindications	Patients who are suspected of having prostate cancer or patients who are not suitable for laser surgery and critically ill patients in other departments. Including the following but not limited to: • The patient's medical history contraindicates anesthesia • Places where tissues (especially tumors) are calcified • For hemostasis of blood vessels over 2 mm in diameter • Out of control bleeding disorders and coagulopathy •Acute urinary tract infection •Severe urethral stricture •Patients with prostate cancer	The use of the Laser System is contraindicated for patients: • Whose general medical condition contraindicates surgical intervention • Where appropriate anesthesia is contraindicated by patient history • Where tissue (especially tumors) has calcified • For hemostatis of vessels over approximately two millimeters in diameter • Where laser therapy is not considered the treatment of choice • Uncontrolled bleeding disorders and coagulopathy • Prostate cancer • Acute urinary tract infection (UTI) • Severe urethral stricture The GreenLight XPS Laser System 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 makes passage of instruments difficult or dangerous. Care should be taken to avoid injury to urethral tissue.	Similar
Composition	The surgical green laser system consists of a semiconductor-pumped ND:YAG green laser head, laser	The laser system consists of a console, which generates the green laser light and a fiber optic delivery device that transmits laser light from the	Similar

	controller, Laser internal circulating cooling system, electronic control system and footswitch.	console to the patient. The console is a diode-pumped Solid State Laser utilizing Nd:YAG laser gain medium and Acousto-Optic Q Switch.	
Laser type	Solid state, frequency doubled, Nd:YAG laser	Solid state, frequency doubled, Nd:YAG laser	Same
Output mode	Multimode	Multimode	Same
Main wavelength (nm)	532	532	Same
Maximum delivered power	PVP-120: 120 W PVP-140: 140 W PVP-160: 160 W PVP-180: 180 W	180W	Similar
Mode of operation	Adjustable	Adjustable	Same
Maximum aiming beam power	5 mW	5 mW	Same
Cooling type	Internal circulating	Internal circulating	Same
Cooling liquid	Deionized water	Distilled or deionized water	Similar
Operation temperature	10° C - 30° C	10° C - 30° C	Same
Relative humidity	30%- 90%	10%- 90%	Similar
Compatible device	Single-use sterile medical laser fiber (model: W760SF-30, B760SF-30, G760SF-30, P760SF-30, W760F-30, B760FF-30, G760FF-30, P760FF-30) manufactured by Realton (Suzhou) Medical Technology Co., Ltd. Laser protective Eyewear Endoscope	GreenLight MoXy™ Fiber Optic Laser protective eyewear Endoscope	Similar
Optical operating	Pulse mode	Pulse mode	Same

modes			
Compatible fibers optical beam area at 2mm	0.48mm^2	0.48mm^2	Same
Compatible fibers applicable wavelength	532nm	532nm	Same
Compatible fibers Maximum optical transmission power	180W	180W	Same

The subject device and the predicate device are similar in the indications for use, contraindications, composition and maximum delivered power. 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.

Performance testing

Performance testing was conducted on surgical green laser system according to IEC 60825-1:2014. Additionally, optical pulse and RF Wireless performance tests were conducted.

Electrical safety, laser safety, and electromagnetic compatibility (EMC)

Electrical safety, laser safety and EMC testing were conducted on the device. The device complies with the ANSI AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text), and IEC 60601-2-22:2007(third edition) + A1:2012 for safety, and the IEC 60601-1-2:2014 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the surgical green laser system and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

8. CONCLUSION

The proposed device is substantially equivalent to the predicate device, GreenLight XPS Laser System, in the laser type, output mode, main wavelength, mode of operation, maximum aiming beam power, cooling type, operation temperature and relative humidity and compatible device. The non-clinical data support the safety of the device and the performance testing report demonstrate that surgical green laser system 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 surgical green laser system is as safe and as effective as the predicate device.