March 25, 2024

Gyrus ACMI, Inc
Andrea Curria
Program Manager, Regulatory Affairs
9600 Louisiana Avenue North
Brooklyn Park, Minnesota 55445

Re: K233275
Trade/Device Name: RenaFlex Single-use Flexible Ureteroscope (SUURF-V Standard);
RenaFlex Single-use Flexible Ureteroscope (SUURF-VR Reverse);
Video System Center for Single-use Endoscopes (CV-S1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: February 27, 2024
Received: February 28, 2024

Dear Julie Acker:

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.

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,

Mark J. Antonino, M.S.
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.

Submission Number *(if known)*

K233275

Device Name

RenaFlex Single-use Flexible Ureteroscope (SUURF-V Standard);
RenaFlex Single-use Flexible Ureteroscope (SUURF-VR Reverse);
Video System Center for Single-use Endoscopes (CV-S1)

Indications for Use *(Describe)*

The RenaFlex™ Single-use Flexible Ureteroscope is intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The Video System Center for Single Use Endoscopes is intended to provide illumination and receive, process, and output images from the compatible Olympus endoscope for diagnostics, treatment, and observation.

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.

510(k) Summary

General Information

Manufacturer:	Gyrus ACMI, Inc. 9600 Louisiana Avenue, North Brooklyn Park, MN 55445 USA Phone: 1-763-416-3000
Establishment Registration Number:	3011050570
510(k) Submitter:	Gyrus ACMI, Inc. 800 West Park Road Westborough, MA 01581
Establishment Registration Number:	3003790304
Contact Person:	Andrea Curria Program Manager, Regulatory Affairs Email: andrea.curria@olympus.com Phone: (508) 262-8682
Date Prepared:	February 26, 2024

Device Description

Classification Name:	Endoscope and Accessories
Regulation Number:	§876.1500
Product Code:	FGB
Regulatory Class:	Class 2
Review Panel:	Gastroenterology/DHT3A
Trade Name:	RenaFlex™ Single-use Flexible Ureteroscope System (RenaFlex Single-use Flexible Ureteroscopes and Video System Center for Single-use Endoscopes)
Generic/Common Name:	Ureteroscope and Accessories/Flexible/Rigid
Model Number:	SUURF-V, SUURF- VR and CV-S1

Predicate Device

Boston Scientific, Inc.
LithoVue System
K153049

Product Description

The RenaFlex Single-use Flexible Ureteroscope System will provide visualization and access for diagnostic and therapeutic applications, including urinary system biopsy and kidney stone treatment and removal. The RenaFlex Single-use Flexible Ureteroscope and compatible Video System Center for Single-use Endoscopes provide a means for direct visualization, diagnosis, and treatment of various

diseases in the urinary tract and kidneys. The ureteroscope component of the system is intended as a single-use device that works to access the anatomy and to guide accessory devices for diagnostic and therapeutic applications in the urinary tract and kidneys. The compatible Video System Center for Single-use Endoscopes is a reusable software-driven device that provides illumination and receives, processes, and outputs images from the endoscope using field upgradable software for diagnosis, treatment, and observation.

Technological Characteristics

The Renaflex Single Use Ureteroscope System provides direct endoscopic access and visualization of the urinary system. For diseases of the urinary system, the ureteroscope enables passage of accessory devices to aid in diagnostic and therapeutic success.

The Renaflex Single Use Ureteroscope System has the same technological characteristics and fundamental design as the predicate device. The Renaflex Single Use Ureteroscope System and the predicate device are designed to provide real-time images to the physician in order to facilitate diagnostic and therapeutic procedures in the urinary tract.

Material

Patient contacting materials is nearly identical to the predicate device and were subject to biocompatibility evaluation against ISO 10993 for a surface-mucosal membrane type contact with limited contact duration (< 24 hours).

Indications for Use

The RenaFlex™ Single-use Flexible Ureteroscope is intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The Video System Center is intended to provide illumination and receive, process, and output images from the compatible Olympus endoscope for diagnostics, treatment and observation.

Compliance to Voluntary Standards

The design of the RenaFlex Single-use Flexible Ureteroscope System complies with the following standards:

Applied standards
IEC 60601-1:2005+AMD1:2012
IEC 60601-1-2 Edition 4.1: 2020
IEC 60601-2-18: 2015
IEC 62366-1, Edition 1.0, 2015
ISO 14971: 2019
ISO 11135: 2014+A1:2018
ISO 11607-1: 2019
ASTM F1980 -21
ISO 10993-1:2018
ISO 10993-7: 2019
ISO 10993-18:2020

Summary of Non-clinical Testing

Shelf-life
Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. All evaluation acceptance criteria were met.

Sterilization
Sterilization validation was carried out in accordance with ISO 11135 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization Processes for Medical Devices”. Sterile barrier systems were evaluated in accordance with ISO 11607 “Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems”. All evaluation acceptance criteria were met.

Biocompatibility
Biocompatibility testing was performed in accordance with the FDA Guidance, Use of international Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following tests were performed, as recommended: Cytotoxicity, Irritation, and Sensitization. Additionally, Acute Systemic Toxicity and Material Mediated Pyrogenicity testing was performed. All evaluation acceptance criteria were met.

Electrical performance
Electrical safety and EMC testing was performed in accordance with IEC 60601-1, “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”, IEC 60601-2-18 “Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment” and IEC 60601-1-2 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”. All evaluation acceptance criteria were met.

Performance

The following performance tests were conducted, and all evaluation acceptance criteria were met:

Mechanical performance
• Insertion Portion Width
• Nuetral Angle
• Maximum Angle of Deflection
• Ureteroscopy Device Compatibility
• Ureteral Access Sheath Compatibility
• Working Channel Flow
• Handle to Connector Tensile Strength
• Overall Weight
• Connector Cable Length
• Working Length
• Working Channel Integrity
• Planarity
• Lever Force
• Minimum Instrument Channel Width/Tool Passage
• Passive deflection
• Shaft Stiffness
• Shaft to Tip Tensile Strength
• Guidewire Compatibility
• Shaft to Handle Tensile Strength

Optical performance
• Signal to Noise Ratio
• Geometric Distortion Test
• Depth of Brightness
• Color Performance
• Field of View
• Video Image Latency
• Resolution
• Image Intensity Uniformity

Human Factors
• Formative and Summative Evaluations

Clinical Studies
Clinical studies were not necessary for substantial equivalence determination.

Substantial Equivalence

Description	Subject Device	Predicate Device (K153049)	Comparison
Name	RenaFlex™ Single-use Flexible Ureteroscope System	LithoVue System	Different
Manufacturer	Olympus Medical	Boston Scientific	Different
FDA Product Code	FGB	FGB	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification Name	Endoscope and accessories	Endoscope and accessories	Same
Intended Use	The RenaFlex™ Single-use Flexible Ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.	The LithoVue System is to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. The LithoVue System consists of the LithoVue Single-Use Digital Flexible Ureteroscope and LithoVue System Workstation all-in-one touchscreen PC– includes monitor workstation, image processing software.	The indications for use statement for the subject device is similar to that of the predicate device. The differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate.
	The RenaFlex™ Single-use Flexible Ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.	The Lithovue System Workstation is intended to provide illumination and receive, process, and output images from the Lithovue ureteroscope for diagnostic and therapeutic applications during endoscopic procedures in urinary system including the kidneys.	
Models	• Standard deflection • Reverse deflection	• Standard deflection • Reverse deflection	Same
Scope Type	Flexible	Flexible	Same
Image Sensor	CMOS	CMOS	Same
Illumination	LED	LED	Same
Prescription/over-the-counter use	Rx Only	Rx Only	Same
Field of View	120° Nominal	120°	Same
Direction of View	0 °Forward Viewing	0 °Forward Viewing	Same
Depth of Field	2-50 mm	2-50 mm	Same
Distal End Outer Diameter	7.7 Fr (2.57 mm)	7.7 Fr (2.57 mm)	Same
Shaft Diameter	9.5 Fr (nominal) 3.23mm (maximum)	9.5 Fr (nominal) 3.23mm (maximum)	Same
Working Length	675mm	68 cm	Same

Description	Subject Device	Predicate Device (K153049)	Comparison
Working Instrument Channel Inner Diameter	ø 1.15 mm (3.6 Fr)	3.6 Fr (nominal) 1.15mm (minimum)	Same
Bending Section Angulation Range	Up/Down 270°	Up/Down 270°	Same
Sterile, single use, disposable	Yes	Yes	Same
Sterilization Method	EO	EO	Same

Conclusion:

In summary, the Gyrus ACMI RenaFlex Single-use Flexible Ureteroscope and Video System Center for Single-use Endoscopes are substantially equivalent to the predicate devices and present no new questions of safety or efficacy.