May 2, 2025

SG Endoscopy Pte Ltd
% Samantha Eakes
Vice President, Regulatory Affairs
Eliquent Life Sciences
1055 Thomas Jefferson St.
Suite 450
Washington, District of Columbia 20007

Re: K243894
Trade/Device Name: F88 URE-SD/RD Flexible Ureteroscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: December 18, 2024
Received: April 11, 2025

Dear Samantha Eakes:

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,

Mark R. Kreitz -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243894

Device Name

F88 URE-SD/RD Flexible Ureteroscope

Indications for Use *(Describe)*

The F88 URE-SD/RD Flexible Ureteroscope and the F88 Flexible Camera Control Unit are indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

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 for the F88 URE-SD/RD Flexible Ureteroscope
SG Endoscopy Pte Ltd

I. SUBMITTER

SG Endoscopy Pte Ltd.

Address: 79 Loyang Way, Singapore, 508766

Contact: John Woo Yeng Jie, Director

Phone Number: +65 8518 3338

Date Prepared: December 18, 2024

II. DEVICE

Name of Device: F88 URE-SD/RD Flexible Ureteroscope
Common or Usual Name: Flexible Ureteroscope
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: Class II
Product Code: FGB – Ureteroscope and Accessories, Flexible/Rigid

III. PREDICATE DEVICE

510(k) Number: K141250
Submitter: Karl Storz Endoscopy-America, Inc.
Name of Device: Flexible Video-Uretero-Renoscope System
Common or Usual Name: Flexible Ureteroscope
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: Class II
Product Code: FGB – Ureteroscope and Accessories, Flexible/Rigid

IV. DEVICE DESCRIPTION

F88 URE-SD/RD Flexible Ureteroscope

The F88 URE-SD Flexible Ureteroscope, Standard Deflection and the F88 URE-RD Flexible Ureteroscope, Reverse Deflection (both also collectively referred to as the "F88 URE-SD/RD Flexible Ureteroscope") is a handheld flexible ureteroscope with a flexible insertion portion length of 670 mm and a maximum outer diameter of 3.05 mm. The device includes a working channel of 1.2 mm diameter for the insertion of various compatible flexible instruments and irrigation systems. The distal tip is equipped with a CMOS imaging sensor and an LED light source for live videos. The control body has a deflection lever to deflect the distal tip up to at least 270° in the up or down directions for navigation and access to targeted areas. The push buttons can be programmed to perform functions such as white balance, brightness, picture, record, zoom and to provide access to the setup menu.

The standard deflection (SD) and reverse deflection (RD) models are functionally identical, with one primary difference: the direction of the distal tip deflection in response to the deflection lever's movement. When the deflection lever of the standard model moves upward, the distal tip deflects upward. In the reverse model, when the deflection lever moves upward, the distal tip deflects downward. The model is selected depending on the handling preference of the user.

The F88 URE-SD/RD Flexible Ureteroscope is a reusable device.

The F88 URE-SD/RD Flexible Ureteroscope is compatible for use with the F88 Flexible Camera Control Unit (FCCU) and several accessories, listed below:

- Single Luer Stopcock
- Vent Cap with Sterilization Card
- Manual Leak Tester
- Luer Port Cleaning Brush
- Cleaning Brush
- URE Working Channel Cleaning Brush

F88 Flexible Camera Control Unit (FCCU)

The F88 Flexible Camera Control Unit (FCCU) or F88 flexible camera console is a device that processes and produces live video images during endoscopic procedures. It is used together with the F88 URE-SD/RD Flexible Ureteroscope and compatible surgical display monitors to form the F88 Flexible Camera System.

V. INDICATIONS FOR USE

The F88 URE-SD/RD Flexible Ureteroscope and the F88 Flexible Camera Control Unit are indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, the F88 URE-SD/RD Flexible Ureteroscope, and the predicate device, the Karl Storz Flexible Video-Uretero-Renoscope, have the identical intended use and indications for use and very similar technological characteristics. The differences in technological characteristics between the two devices are minor and do not raise different questions of safety and effectiveness. Comprehensive performance testing has been conducted on the subject device to address the minor differences in technological characteristics and to demonstrate that the subject device performs as intended and has

the same or better performance than the predicate device. This includes comparative testing with the predicate device.

Device	Flexible video endoscope with video processor (Subject device)	Flexible Video-Uretero-Renoscope System (Predicate device)	Comparison
Trade Name	F88 URE-SD/RD Flexible Ureteroscope	FLEX-XC Flexible Video-Uretero-Renoscope System	N/A
510(k) Number	TBD	K141250	N/A
Device Classification	Class II	Class II	Identical
FDA Regulation number	21 CFR 876.1500	21 CFR 876.1500	Identical
Product Code	FGB	FGB	Identical
Indications for Use	The F88 URE-SD/RD Flexible Ureteroscope and the F88 Flexible Camera Control Unit are indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney and using additional accessories, to perform various diagnostic and therapeutic procedures.	The KARL STORZ Flexible Video-Uretero-Renoscope System is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.	Identical (except for device names)
Patient contact materials	Biocompatible materials	Biocompatible materials	Similar Biocompatibility testing was successfully conducted in accordance with ISO 10993-1 on all patient contacting materials
Reusable	Yes	Yes	Identical
Sterilization method	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide	Identical
No. of working channel(s)	1	1	Identical
Working channel diameter	1.2mm	1.2mm	Identical
Working channel length	670 mm	675 mm	Similar. The minor difference in working length does not affect safety or effectiveness. Performance testing demonstrated that the subject device met its required specifications.
Outer Diameter of distal tip	9.15 Fr	8.5 Fr	Similar. The minor difference in outer diameter

			of the distal tip does not affect safety or effectiveness. Performance testing demonstrated that the subject device met its required specifications.
Outer Diameter of insertion tube	2.85 mm	2.9 mm	Similar. The minor difference in outer diameter of the insertion tube does not affect safety or effectiveness. Performance testing demonstrated that the subject device met its required specifications.
Configuration	F88 URE-SD > Standard Deflection; F88 URE-RD > Reverse Deflection	11278 VSA > Positive Deflection; 11278 VSUA > Contrapositive Deflection	Identical. Both ureteroscopes are available in standard and reverse deflection models.
Deflection angles	≥ 270° Up / ≥ 270° Down	≥ 270° Up / ≥ 270° Down	Identical
Image sensor at distal tip	CMOS	CMOS	Identical
Light source	LED integrated in handle	LED integrated in handle	Identical
Direction of view	0°	0°	Identical
Field of view (diagonal)	106°	90°	Similar The subject device has a slightly wider field of view. This difference does not affect safety or effectiveness.
Depth of view	2 – 50 mm	4 – 60 mm	Similar. The difference in depth of view is minor and does not affect safety or effectiveness. The depth of view of the subject device is within the range for other 510(k) cleared ureteroscopes.
Powered by	FCU-200	IMAGE 1 S X-LINK (TC301); IMAGE 1 S CONNECT (TC 200)	Similar Each device is powered by its own method specific to the device. The difference in power source does not impact safety and effectiveness.

Power source	100 – 240VAC 50 – 60Hz	100 – 240VAC 50 – 60Hz	Identical
White balance	Manual	Manual	Identical
Brightness control	Yes	Yes	Identical
Image enhancement	Yes	Yes	Identical
Image/Video capture	No	Yes	Different Unlike the predicate device, the subject device is designed to not store any images or video recordings. This difference does not impact safety and effectiveness.
Record to memory card	No	USB Flash Drive 32 GB	Different Unlike the predicate device, the subject device does not have a feature to record data to a memory card. This difference does not impact safety and effectiveness.
Water ingress protection	IPX0	IPX0	Identical

VII. PERFORMANCE DATA

The following performance testing was successfully completed for the F88 URE-SD/RD Flexible Ureteroscope and the F88 Flexible Camera Control Unit (FCCU) to establish the safe and effective use of the device and to demonstrate substantial equivalence to the predicate device:

Biocompatibility Testing:

The biocompatibility evaluation for the F88 URE-SD/RD Flexible Ureteroscope was conducted in accordance with ISO 10993-1 and FDA's guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* The device is considered an external communicating device, tissue/bone/dentin contacting with a limited contact duration $\leq$ 24 hours. Testing was conducted on both non-sterile and cleaned/sterilized devices reprocessed after the recommended number of reprocessing cycles. Testing included the following:

- Cytotoxicity
- Sensitization

- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Cytotoxicity testing was also conducted for the Single Luer Stopcock.

Reprocessing Validation:

Reprocessing validation including cleaning and sterilization validation and human factors testing was completed for the F88 URE-SD/RD Flexible Ureteroscope. Cleaning validation was completed for the F88 Flexible Camera Control Unit (FCCU). Steam Sterilization Validation was also completed for the Single Luer Stopcock.

Electrical Safety and Electromagnetic Compatibility (EMC):

Electrical Safety and EMC testing was completed for the F88 Flexible Camera Control Unit (FCCU). The device complies with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing:

Software verification and validation testing was completed for the F88 Flexible Camera Control Unit (FCCU), and documentation was provided in accordance with FDA's guidance, *Content of Premarket Submissions for Device Software Functions*. The software documentation level was basic. Software testing included system verification, installation testing, integration testing, unit testing and user acceptance testing.

Cybersecurity Testing:

Cybersecurity testing was completed for the F88 Flexible Camera Control Unit (FCCU), and documentation was provided in accordance with FDA's guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*. A vulnerability assessment was conducted, and penetration testing was completed.

Additional Performance Testing:

Additional performance testing was completed for the F88 URE-SD/RD Flexible Ureteroscope and the F88 Flexible Camera Control Unit (FCCU) as outlined below:

F88 URE-SD/RD Flexible Ureteroscope
- Design Verification
- Simulated Transportation Validation in accordance with ASTM D4169-23e1
- Comparative testing with the predicate device

F88 Flexible Camera Control Unit (FCCU)

- Design Verification
- Electromagnetic Compatibility in accordance with IEC 60601-1-2:2014+A1:2020 (Ed4.1) and IEC TR 60601-4-2
- Control Unit Feature Verification
- System Reliability Testing
- Video Performance and Timing
- RF Interference
- Simulated Transportation Validation in accordance with ASTM D4169-23e1

Animal Testing:

Animal testing was not required to demonstrate substantial equivalence to the predicate device.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

VIII. CONCLUSIONS

The information provided in this 510(k) submission demonstrates that the F88 URE-SD/RD Flexible Ureteroscope has the identical indications for use and the same overall technological characteristics as the predicate device. The performance testing demonstrates that the device is as safe, as effective, and performs as well or better than the predicate device. In conclusion, the subject device is substantially equivalent to the predicate device, the Karl Storz Flexible Video-Uretero-Renoscope (K141250).