March 27, 2025

Scivita Medical Technology Co., Ltd.
Dan Jiang
Senior Regulatory Affairs Specialist
No.2, Qingqiu Street, Suzhou Industrial Park
Suzhou, Jiangsu 215000
CHINA

Re: K243708
Trade/Device Name: Urology Videoscope System (Single-use Flexible Ureteroscope: SUV-1A-B, SUV-1A-P, SUV-2A-B, SUV-2A-P, SUV-2B-B, SUB-2B-P, SUV-2C-B, SUV-2C-P;Single-use Flexible Cystoscope: SUV-1D-B, SUV-1D-P; Endoscopic Image Processor: HDVS-S100A, HDVS-S100D.)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FAJ
Dated: February 28, 2025
Received: February 28, 2025

Dear Dan Jiang:

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 J. Antonino -S

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)*

K243708

Device Name

Urology Videoscope System
(Single-use Flexible Ureteroscope: SUV-1A-B, SUV-1A-P, SUV-2A-B, SUV-2A-P, SUV-2B-B, SUB-2B-P, SUV-2C-B, SUV-2C-P;Single-use Flexible Cystoscope: SUV-1D-B, SUV-1D-P; Endoscopic Image Processor: HDVS-S100A, HDVS-S100D.)

Indications for Use *(Describe)*

This Single-use Flexible Ureteroscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the urinary system such as urethra, bladder, ureter and renal pelvis.

This Single-use Flexible Cystoscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the urinary system such as urethra, bladder and renal pelvis.

This Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on the monitor detected within the field of view from the body cavity.

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) #: K243708

510(k) Summary

Prepared on: 2025-03-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co.,Ltd.
Applicant Address	No.2, Qingqiu Street, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R.CHINA Suzhou 215000 China
Applicant Contact Telephone	86-512-81877788
Applicant Contact	Mrs. Ruqin Wu
Applicant Contact Email	wuruqin@scivitamedical.com
Correspondent Name	Scivita Medical Technology Co.,Ltd.
Correspondent Address	No.2, Qingqiu Street, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R.CHINA Suzhou Suzhou 215000 China
Correspondent Contact Telephone	86-512-81877788
Correspondent Contact	Ms. Dan Jiang
Correspondent Contact Email	ra@scivitamedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Urology Videoscope System (Single-use Flexible Ureteroscope: SUV-1A-B, SUV-1A-P, SUV-2A-B, SUV-2A-P, SUV-2B-B, SUB-2B-P, SUV-2C-B, SUV-2C-P;Single-use Flexible Cystoscope: SUV-1D-B, SUV-1D-P; Endoscopic Image Processor: HDVS-S100A, HDVS-S100D.)
Common Name	Endoscope and accessories
Classification Name	Ureteroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FGB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172098	Medical Video Endoscope System	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Urology Videoscope System is consisting of a Single-use Flexible Ureteroscope (SUV-1A-B, SUV-1A-P, SUV-2A-B, SUV-2A-P, SUV-2B-B, SUB-2B-P, SUV-2C-B, SUV-2C-P) or Single-use Flexible Cystoscope (SUV-1D-B, SUV-1D-P) and an Endoscopic Image Processor (HDVS-S100A, HDVS-S100D) including the foot switch. The subject device has been designed to be used for endoscopic diagnosis and therapies within the urinary system such as urethra, bladder, ureter and renal pelvis.

The Single-use Flexible Ureteroscope and Single-use Flexible Cystoscope are single use devices. They are intended to be used in

conjunction with Endoscopic Image Processor to provide images thr ough the video monitor for observation, diagnosis, photography and treatment of the urinary system such as urethra, bladder, ureter and renal pelvis. There are ten models of Single-use Flexible Ureteroscope and Single-use Flexible Cystoscope, with four kinds of insertion portion widths (2.5mm, 2.7mm, 2.8mm and 5.4 mm), four working lengths (380mm, 550mm, 635mm and 680mm), two differe nt material of the insertion section (Nylon and PEEK) and with or without suction section.

The Single-use Flexible Ureteroscope and Single-use Flexible Cystos cope are single-channel endoscope. Only one working channel is in the distal end of the endoscope, and it bifurcates to two channels le ading to the irrigation valve and suction section.

The Single-use Flexible Ureteroscope and Single-use Flexible Cystos cope are sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied sterility maintenance package which could maintain th ıe sterility of the device during the shelf life of three years.

The Endoscopic Image Processor is a reusable device. The Endoscop ic Image Processor has two models. The only difference between the two models is that the HDVS-S100A has Enhance function and the H DVS-S100D does not have the Enhance function.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This Single-use Flexible Ureteroscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the urinary system such as urethra, bladder, ureter and renal pelvis.

This Single-use Flexible Cystoscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the urinary system such as urethra, bladder and renal pelvis.

This Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on the monitor detected within the field of view from the body cavity.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject device and predicate device are used for endoscopic diagnosis and therapies within the urinary system. The subject and predicate device contain no differences in intended use, they are both Ureteroscopes and Cystoscopes that obtain visualization with an image processor.

Technological Comparison

21 CFR 807.92(a)(6)

The subject endoscope Single-use Flexible Ureteroscope or Single-use Flexible Cystoscope and the predicate Uscope (K172098) share the similar technological characteristics, including one CMOS image sensors for visualization, two LED illumination light modules for lighting and a working channel in the distal end of the endoscope.

The technological characteristics difference between the subject and predicate endoscope is only in dimensions, such as depth of field, outer diameter of insertion section, up/down deflection, working length and inner diameter instrument channel. These differences do not raise different questions of safety and effectiveness of the subject device.

The subject image processor is basically the same as the predicate Eview (K172098) in technological characteristic. Both of them receive the signals from endoscope and transmit them to the monitor and display endoscope image on the monitor. They are different in video signal output interface. This difference will not affect the safety and effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination. The test results demonstrated that the subject device complies with the standard requirements.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing: The electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1 :2005+A 1 :2012+A2:2020, IEC 60601-2-18:2009 and IEC 60601-1-2:2014+A 1 :2020.

Biocompatibility Testing The biocompatibility tests were conducted in accordance with the requirements of ISO 10993-1 and FDA guidance, including Cytotoxicity (ISO 10993-5:2009), Sensitization (ISO 10993-10:2021), Irritation (ISO 10993-23:2021), Acute Systemic Toxicity (ISO 10993-11 :2017) and Pyrogen (I SO 10993-11:2017) tests.

ISO 8600 Testing
The subject device was designed to comply with applicable parts of ISO 8600-1: 2015, ISO 8600-3:2019, ISO 8600-4: 2014.

Optical performance:
Optical performance comparison testing was conducted on the subject device and predicate device. The optical performance test items include Field of View & Direction of View, Signal-Noise Ratio & Dynamic Range, Color Reproduction, Geometric Distortion, Image Frame Frequency & System Delay, Intensity Uniformity, Depth of Field & Resolution.

Mechanical Performance Testing:
The mechanical performance testing was conducted to demonstrate the subject endoscope can function as intended. The mechanical performance testing includes the leakage testing and suction testing.

Shelf Life and Service Life (Use Life):
The use-life of image processor is six years. The use-life of the image processor has been demonstrated in K210379.

Photobiological safety:
The photobiological safety testing was tested in accordance with IEC 62471:2006.

Software and Cybersecurity Testing:
Software verification and validation testing and cybersecurity testing were conducted on the device, and the documentation was provided as recommended by FDA's guidance, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions".

The clinical data is not applicable.

The nonclinical test were conducted to demonstrate that the subject is as safe and effective as the predicate.