August 14, 2026

Scivita Medical Technology Co., Ltd.
Mengxuan Yuan
Senior Regulatory Specialist
2, Qingqiu St., Suzhou Industrial Park
Suzhou, Jiangsu Prov. 215000
CHINA

Re: K262552
Trade/Device Name: Single-use Flexible Ureteroscope (Single-use Flexible Ureteroscope: SUV-5C-B)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: July 23, 2026
Received: July 24, 2026

Dear Mengxuan Yuan:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262552

Please provide the device trade name(s).

Single-use Flexible Ureteroscope (Single-use Flexible Ureteroscope: SUV-5C-B)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-08-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co.,Ltd.
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Correspondent Name	Scivita Medical Technology Co.,Ltd.
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Correspondent Contact Telephone	86-512-81877788
Correspondent Contact	Mr. Mengxuan Yuan
Correspondent Contact Email	ra@scivitamedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Single-use Flexible Ureteroscope (Single-use Flexible Ureteroscope: SUV-5C-B)
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
K243708	Single-use Flexible Ureteroscope	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Single-use Flexible Ureteroscope is single use devices. It 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.

There is one model of Single-use Flexible Ureteroscope, with insertion portion widths (2.5mm), working lengths (680mm), material used Glass, Sulfone polymer, 304 SUS, Pebax, PET, PA12, PC, Silicone rubber.

The Single-use Flexible Ureteroscope is single-channel endoscope. Only one working channel is in the distal end of the endoscope and

lead to the irrigation valve.

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

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject device is the same as predicate device. Both the subject device and predicate device are used for endoscopic diagnosis and therapies within the urinary system.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technical characteristics as the predicate device. They have the same specifications, designed structure and materials. This submission is intended to create a new model Single-use Flexible Ureteroscope SUV-5C-B by deflection direction modification of the existing device Single-use Flexible Ureteroscope model SUV-2C-B (K243708) for market needs to adapt to the operators' different operating habit when holding the Single-use Flexible Ureteroscope.
The endoscope has two traction wires in operation section used to adjust distal end's deflection direction. Compared with SUV-2C-B, SUV-5C-B transposes install these two traction wires to achieve opposite deflection direction to SUV-2C-B.
The only differences between model SUV-5C-B and SUV-2C-B are the different deflection directions, and the indications for use, material, specifications and processes are the same.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The only differences between proposed new model Single-use Flexible Ureteroscope SUV-5C-B and the predicate Device Single-use Flexible Ureteroscope SUV-2C-B are the different deflection directions. Different deflection directions may affect deflection angle, the manufacture conduct ISO 8600-I test for deflection angle verification. The subject device was designed to comply with applicable parts of ISO 8600-1:2025 (surface and edges, Angle of deflection Test), ISO 8600-3:2019 (Field of View and Direction of View), ISO 8600-4:2023 (Maximum insertion portion width).

Also, regarding EMC and electrical safety testing, manufacture refreshed IEC60601-1, IEC60601-2-18 and IEC 60601-1-2 test report of Single-use Flexible Ureteroscope SUV-2C-B to cover this new model SUV-5C-B and applied NRTL certificate by OSHA recognized NRTL.

The clinical data is not applicable.

The non-clinical test were conducted to demonstrate that the subject is as safe and effective as the predicate. All other relevant testing was leveraged from the predicate submission (K243708).