May 6, 2025

Hunan Vathin Medical Instrument Co.Ltd
Charlene Du
RA Manager
1/F, Building 12,Innovation and Entrepreneurship Service Ctr
No 9 Chuanqi west road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
CHINA

Re: K250785
Trade/Device Name: Single-use Flexible Ureteroscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: March 14, 2025
Received: March 14, 2025

Dear Charlene Du:

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)*

K250785

Device Name

Single-use Flexible Ureteroscope

Indications for Use *(Describe)*

The Single-use Flexible Ureteroscope is designed for use with Vathin Display Units, endotherapy accessories and other ancillary devices for the endoscopy and endoscopic surgery within urinary tract and kidney in adults.

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

I Submitter

Device submitter:	Hunan Vathin Medical Instrument Co., Ltd.
Address:	1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
Contact person:	Du Jing Title: RA Manager Phone: +86-18915069265 E-mail: charlene@vathin.com
Date prepared	March 12, 2025

II Device

Name of Device:	Single-use Flexible Ureteroscope
Common name	Single-use Flexible Ureteroscope
Models	US-S2602, US-E2602, US-S2602R, US-E2602R
Classification name:	Ureteroscope and Accessories, Flexible/rigid (21 CFR 876.1500)
Regulatory class:	Class II
Product code:	FGB

III Predicate Device

Trade name:	Uscope
Classification name:	Ureteroscope and Accessories, Flexible/rigid (21 CFR 876.1500)
Regulatory class:	Class II
Product code:	FGB
Submitter:	Zhuhai Pusen Medical Technology Co., Ltd.
510(k) number:	K172098

IV Device description

The Sinle-use Flexible Ureteroscope is intended to be used with Vathin Digital Video Monitor. During diagnosis and treatment, the Single-use Flexible Ureteroscope is inserted into the ureter or into the kidney or renal pelvis through the ureter, and the image sensor (CMOS) at the end of the Single-use Flexible Ureteroscope converts the received mucosal reflected light signals into electrical signals ,

transmitted to the Digital Video Monitor through the cable, the Digital Video Monitor receives the image signal from the endoscope and processes it, converts it into an image signal that can be displayed on the display screen, and finally presents it on the screen of the display.

The Single-use Flexible Ureteroscope is provided sterile (sterilized by EO) and intended to be single-use. It is for use in professional Healthcare Facility Environment.

V Indications for use

The Single-use Flexible Ureteroscope is designed for use with Vathin Display Units, endotherapy accessories and other ancillary devices for the endoscopy and endoscopic surgery within urinary tract and kidney in adults.

VI Comparison of technological characteristics with the predicate devices

The Single-Use Flexible Ureteroscope is similar to the predicate device in the following areas:

- Intended use
- Operation Principle
- Design and performance specifications
- Digital video technology and illumination source
- It allows for irrigation
- It is single-use and delivered sterile

The Single-Use Flexible Ureteroscope is different to the predicate device in the following areas:

- Larger bending angle, minimum inner diameter of instrument channel
- Longer working length
- Smaller maximum outer diameter

The differences between the Single-Use Flexible Ureteroscope and predicate device do not alter suitability of the subject device for its intended use.

Device feature	Subject Device	Predicate Device
Trade Name	Single-Use Flexible Ureteroscope	Uscope (K172098)
Classification Name	Endoscope and accessories	Endoscope and accessories
Product Code	FGB	FGB
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Intended use	The Single-use Flexible Ureteroscope is designed for use with Vathin Display Units, endotherapy accessories and	This instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other

Device feature	Subject Device	Predicate Device
	other ancillary devices for the endoscopy and endoscopic surgery within urinary tract and kidney in adults.	ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.
Compatible Display Unit	Digital Video Monitor, DVM-B1, K231135	Eview, UTV100
Application field	The device is for use in a hospital or qualified medical institution.	The Medical Video Endoscope system is for use in a hospital or qualified medical institution.
Intended user	The device is only to be used by skilled medical staff trained in clinical endoscopic techniques and procedures.	The system is only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.
Patient population	Adults	Adults
Scope type	Flexible	Flexible
Field of view	120°	120°
Direction of view	0°	0°
Bending angle	Up: 285° Down: 285°	Up: 270° Down: 270°
Maximum outer diameter of insertion part (mm)	2.8	3.2
Minimum inner diameter of instrument channel (mm)	1.2	1.0
Working length (mm)	700	650
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibili	No Cytotoxicity	No Cytotoxicity

Device feature	Subject Device	Predicate Device
ty	No Irritation to Skin No significant evidence of sensitization	No Irritation to Skin No significant evidence of sensitization
Sterilization	EO	EO

VII Summary of Non-clinical tests:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Single-Use Flexible Ureteroscope was conducted in accordance with "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The Single-use Flexible Ureteroscope is considered for mucosal membrane contacting for a duration of less than 24 hours. The following tests were performed as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the IEC 60601-1 and IEC60601-2-18 standards for safety and the IEC 60601-1-2, IEC 60601-4-2 standards for EMC.

Sterilization validation

EO sterilization of the Single-Use Flexible Ureteroscope has been validated according to ISO 11135.

Shelf life and Packaging testing

Shelf life and sterile barrier system of the Single-Use Flexible Ureteroscope have been validated. Packaging integrity testing and product performance testing were carried out following the accelerated aging of the final devices per ASTM F1980-21 and simulated transportation distribution according to ASTM D4169-22.

Bench performance testing

Bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to the predicate device. The following performance testing was conducted.

Bench testing - Mechanical Performance
The mechanical performance testing was conducted in accordance with applicable parts of ISO 8600-1, ISO 8600-4.

Bench testing – Optical Performance
- Field of view
- Direction of view
- Depth of field
- Geometric distortion
- Image intensity uniformity
- Color performance
- Signal-To-Noise Ratio
- Dynamic Range

Bench testing – Photobiological Safety
The subject device was tested according to FDA recognized standards IEC 62471:2006.

VIII Conclusion

The device is substantially equivalent to predicate device. The non-clinical performance testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed predicate device.