May 18, 2023

Hunan Vathin Medical Instrument Co., Ltd.
Du Jing
RA Manager
1/F, Building 12, Innovation Entrepreneurship Service Center
No.9 Chuanqi West Road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
China

Re: K230200
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: April 18, 2023
Received: April 19, 2023

Dear Du Jing:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230200

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.

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Section 5 510(k) summary

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

Device

Trade Name of Device: Single-use Flexible Ureteroscope
Common name: Ureteroscope and Accessories, Flexible/rigid
Classification name: Endoscope and accessories
Classification: Class II, 21 CFR 876.1500
Product Code: FGB
Review Panel: Gastroenterology/Urology
Date prepared: January 18, 2023

Predicate Device

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

Device description

The Single-use Flexible ureteroscope can be connected to the compatible Vathin Display Units and other accessories for the endoscopy and endoscopic surgery within urinary tract and kidney in adults. The Single-use Flexible ureteroscope is provided sterile (sterilized by EO) and intended to be single-use.

The compatible Digital Video Monitor:
Model: DVM-A1

The Single-use Flexible ureteroscope and Display Unit make up the video ureteroscope system. During diagnosis and treatment with the video ureteroscope system, 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 Display Unit through the cable, the Display Unit 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.

There are 4 models of Single-Use Flexible Ureteroscope, the difference between US-S170 and US-E170,US-S180 and US-E180 lies in the US-SXXX series with self-lock and suction function, US-EXXX series does not come with self-lock and suction functions, the rest is exactly the same. The difference between the 2 models of US-EXXX series lies in work channel ID, head OD and outer diameter of main hose OD, while the rest are exactly the same. The difference between the 2 models of US-SXXX series also lies in work channel ID, head OD and outer diameter of main hose OD, and the rest are the same.

The Single-use Flexible Ureteroscope includes insertion part, control part, connection part. The control part is made with ABS, contacted with users. The insertion part, as the part connected with patients, includes the sheath which is braided tube made with PEBAX tube, the bending section and the distal end. The bending section is made of snake bone, covered with snake bend eraser. The distal end is made of sensor and LED.

Indications for use

The indications for use of subject and predicate device are the same. Both of the subject and predicate device are indicated for endoscopy and endoscopic surgery within urinary tract and kidney. The indications for use of subject device: 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. The indications for use of predicate device: This instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

Comparison of technological characteristics with the predicate devices

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

- Intended use (including application field, intended user and patient population)
- Principal operation
- 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:

- The bending angle is larger than the predicate
- There are 4 specifications while predicate device has 2 specifications
- Working length is 700mm while working length of predicate device is 650mm

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

Device feature	**Proposed Device**	**Predicate Device**
Trade Name	**Single-Use Flexible Ureteroscope**	**Medical Video Endoscope system(K172098)**
Classification Name	Endoscope and accessories	Endoscope and accessories
Product Code	FGB	FGB
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
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.	This instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.
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.

Device feature	Proposed Device	Predicate Device
Trade Name	**Single-Use Flexible Ureteroscope**	**Medical Video Endoscope system(K172098)**
Patient population	Adults	Adults
Scope type	Flexible	Flexible
Field of view (degree)	110°	120°
Direction of view (degree)	0°	0°
Bending angle (degree)	Up: 285◦ Down: 285°	Up: 270◦ Down: 270°
Maximum insertion portion width(mm)	US-S170、US-E170：3.15 US-S180、US-E180：3.25	3.2
Minimum insertion channel width(mm)	US-S170、US-E170：1.2 US-S180、US-E180：1.4	1.0
Working length (mm)	700	650
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibility	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization
Sterilization	EO	EO

Summary of Non-clinical tests:

Biocompatibility testing

Biocompatibility of the Single-Use Flexible Ureteroscope was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "breached or compromised surface" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity. All evaluation acceptance criteria were met.

Sterility testing

Sterile barrier systems were evaluated in accordance with ISO 11607.
Sterilization Process has been validated accordance with ISO 11135.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Single-Use Flexible Ureteroscope. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Performance testing

The following performance testing was conducted on the Single-Use Flexible Ureteroscope.

Functional performance

- Appearance
- Working length
- Work channel ID
- Head OD
- Outer diameter of main hose
- Maximum outer diameter of the insertion part
- Bending angle
- Product weight
- Rotating sleeve
- Handle-based photographing function
- Self-locking function
- Wire length
- Image display
- Waterproofness
- Lens fogging
- Image quality
- LED illuminance test
- LED color temperature test
- Air tightness test
- Suction ability
- Water delivery ability

- LED temperature test

Mechanical performance

- Handle-based camera button reliability test
- Passively bent part reliability test
- Self-locking component reliability test
- Insertion end tension
- Pull out tension of plug end

Optical performance

- Direction of view
- field of view test
- observation depth of field test
- geometric distortion test
- SNR test
- dynamic tolerance test
- brightness uniformity test

Color performance

- color restoration test

Conclusion

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