April 9, 2026

Anhui Happiness Workshop Instruments Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
CHINA

Re: K252929
Trade/Device Name: Single Use Digital Flexible Ureteroscope (7.5F); Videoscope Imaging Processor (Model HV-200)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FET
Dated: September 15, 2025
Received: Septembr 15, 2025

Dear Boyle Wang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K252929

Please provide the device trade name(s).

Single Use Digital Flexible Ureteroscope (7.5F);
Videoscope Imaging Processor (Model HV-200)

Please provide your Indications for Use below.

Single Use Digital Flexible Ureteroscope (7.5F) is intended to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The Videoscope Imaging Processor, when used with the endoscope, provides imaging for the examination, diagnosis, or treatment of urinary tract conditions.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K252929

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Date of Preparation: April.7th,2026

2.0 Device Information

Trade name: Single Use Digital Flexible Ureteroscope (7.5F)
Videoscope Imaging Processor (Model HV-200)
Common name: Endoscope and accessories
Classification name: Ureteroscope And Accessories, Flexible/Rigid
Production code: FGB, FET
Regulation number: 21 CFR 876.1500
Classification: Class II
Panel: Gastroenterology/Urology

3.0 Predicate Device Information

Predicate#

Manufacturer: Zhuhai Pusen Medical Technology Co, Ltd.
Trade name: Pusen Single Use Flexible Video Ureteroscope (Model: PU3033H, PU3033AH) and Pusen Single Use Suction Access Ureteroscope (Model: PU400A, PU411A)
510(k) number: K233778
Product code: FGB
This predicate device has not been subject to a design-related recall.

4.0 Indication for Use Statement

Single Use Digital Flexible Ureteroscope (7.5F) is intended to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The Videoscope Imaging Processor, when used with the endoscope, provides imaging for the examination, diagnosis, or treatment of urinary tract conditions.

5.0 Device Description

The Digital Endoscope System is consists of the Single Use Digital Flexible Ureteroscope (7.5F) and a Videoscope Imaging Processor (HV-200). The Single Use Digital Flexible Ureteroscope (7.5F) is powered and controlled through connection to the Videoscope Imaging Processor (HV-200), which provides illumination, processes the video signal, and outputs images to an external monitor. Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney.

The Single Use Digital Flexible Ureteroscope (7.5F) (Model HUS-T101R, HUS-T102R,HUS-T101S,HUS-T102S) and Videoscope Imaging Processor (Model HV-200) have been designed to be used with each other for physicians to access, visualize, and perform procedures in the urinary tract for diagnosis and treatment.

The Single Use Digital Flexible Ureteroscope (7.5F) is a sterile, single-use, flexible, digital video ureteroscope. It is comprised of a control body with articulation controls and accessory access ports, and a flexible insertion tube with an on-tip camera module (CMOS) and LED lighting source. The diameter of the Insertion portion is 7.5Fr, which is thinner than conventional endoscopes.

Single Use Digital Flexible Ureteroscope (7.5F) is the accessory and detachable part of Videoscope Imaging Processor. Single Use Digital Flexible Ureteroscope (7.5F) has 4 models, HUS-T101R, HUS-T102R, HUS-T101S and HUS-T102S, and can be operated by either left or right hand. The model information is shown as Table 1

Product Model:

Table 1 Product Models

Product Model	Description	Allowance
HUS-T101R	Working length 670mm with reverse deflection	+10mm
HUS-T102R	Working length 660mm with reverse deflection	+10mm
HUS-T101S	Working length 670mm with standard deflection	+10mm
HUS-T102S	Working length 660mm with standard deflection	+10mm
Note: 'S' means standard deflection; 'R' means reverse deflection.		

Figure 1 Standard Deflection

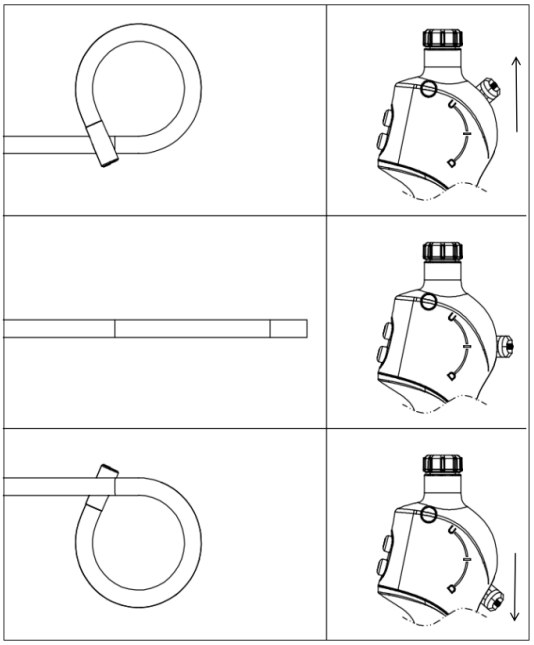
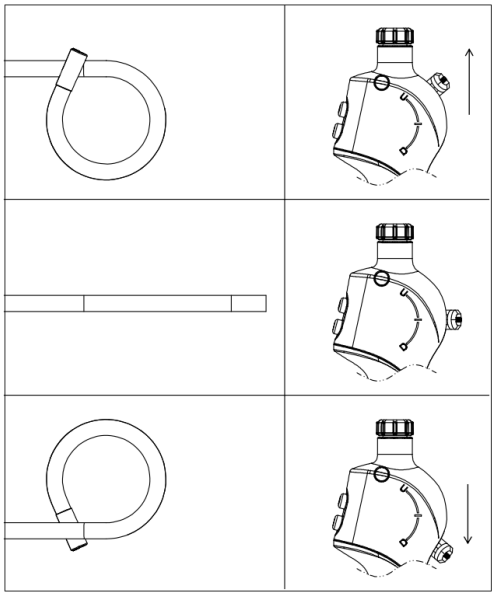


Figure 2 Reverse Deflection



The Videoscope Imaging Processor is composed of processor, power cord and HDMI video cables. The Processor processes the signal from the endoscope and outputs video signals to a monitor.
The processor provides the necessary power and control to the ureteroscope's LED light source and CMOS image sensor, processes the captured video signals, and outputs real-time images to external monitors via HDMI, DVI, or SDI connections. Front panel controls allow power switching, menu navigation, photo capture (JPG), video recording (AVI), image freezing, zoom, LED brightness adjustment, and white balance calibration.
The HV-200 Videoscope Imaging Processor is a reusable device and do not require sterilization before use.

Together, the reusable Videoscope Imaging Processor and the Single Use Digital Flexible Ureteroscope (7.5F) together complete the Digital Endoscope System enabling a Flexible Ureteroscopy procedure to take place.

6.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K252929	Predicate Device K233778
Product Name	Single Use Digital Flexible Ureteroscope (7.5F) Videoscope Imaging Processor (Model HV-200)	Single Use Flexible Video Ureteroscope Single Use Suction Access Ureteroscope
Product Code	FGB, FET	FGB
Regulation No.	21 CFR 876.1500	21 CFR 876.1500
Class	Class II	Class II
Model	Single Use Digital Flexible Ureteroscope (7.5F): HUS-T101R; HUS-T102R; HUS-T101S; HUS-T102S Videoscope Imaging Processor: HV-200	PU400A; PU411A PU3033H; PU3033AH
Intended Use/Indication for Use	Single Use Digital Flexible Ureteroscope (7.5F) is intended to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. The Videoscope Imaging Processor, when used with the endoscope, provides imaging for the examination,	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. This instrument is also used as a suction catheter that establishes a conduit used for irrigation and aspiration of kidney stones and stone dust during ureteral lithotripsy

	diagnosis, or treatment of urinary tract conditions.	
Target population	Adults	Adults
Single Use Digital Flexible Ureteroscope		
Scope type	Flexible	Flexible
Scope reusability	Single-use	Single-use
Energy used	Powered by line power	Powered by chargeable battery or line power.
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Field of view	110°	120°
Direction of view	0°	0°
Depth of field	2-50 mm	3~50 mm
Maximum insertion portion width	2.85mm	PU3033AH, PU3033H: 2.7 mm PU400A, PU411A: 3.2
Working length	HUS-T101R, HUS-T101S: 670mm HUS-T102R,HUS-T102S: 660mm	PU3033AH, PU3033H: 650 mm； PU400A: 650 mm； PU411A: 680 mm
Working channel size	≥3.6Fr (1.2mm)	PU3033AH, PU3033H: ≥1.2 mm； PU400A, PU411A: ≥5.1 Fr
Up/down deflection	Up:285° Down:285°	Up: 270° Down: 270°
Irrigation	Provided	Provided
Suction	Not Provided	Provided
Sterility	Ethylene Oxide (EO) SAL: 10^{-6}	Ethylene Oxide (EO) SAL: 10^{-6}
Image system	Videoscope Imaging Processor (Model HV-200)	Processor PV300(Cleared under K222602)

7.0 Non-clinical Testing Summary

The following performance data have been conducted to verify that the subject device meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Conclusions for Biocompatibility Testing

The biocompatibility evaluation for the Single Use Digital Flexible Ureteroscope (7.5F) was conducted in accordance with the FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process'" and FDA recognize international standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process". The worst case of the Ureteroscope is considered breached/compromised or compromised surfaces, contacting tissue for a limited duration (< 24 hours).

And the testing included the following tests, results of which demonstrate the

biological safety of the subject device:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-23)
- Material-Mediated Pyrogenicity(ISO 10993-11)
- Acute Systemic Toxicity(ISO 10993-11)

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

➢ IEC 60601-1:2005/AMD2:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

➢ IEC 60601-1-2:2020, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances - Requirements and tests

➢ IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

➢ IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Summary of Bench Testing

Bench testing was conducted and the results show that the subject device complies with the below standard:

➢ Mechanical and Optical Performance

--Deflection performance
--Working channel performance
--Flow rate
--Tensile and torsional strength
--Field of view
--Direction of view
--Resolution
--Noise and dynamic range
--Geometric distortion
--Image intensity uniformity

➢ Image Quality

Comparative testing related to image quality performances including color performance (color reproduction and color contrast enhancement), optical performance (resolution, depth of field, image intensity uniformity and distortion) tests were performed for the subject device and the predicate device to support substantial equivalence.

- Photobiological Safety

The LEDs in the subject device were tested according to the following FDA recognized standards:

• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems.

- Luer taper

Luer taper in the subject device was tested according to ISO 80369-7: 2021, Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions.

The Software Validation is in compliance with FDA Guidance.

Summary of Sterilization and Shelf Life

-- Sterilization Process has been validated accordance with ISO 11135:2014;

-- EO/ECH residual test was performed according to ISO 10993-7:2008

--Environmental conditioning and simulated shipping distribution according to ASTM D4169-23

-- The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The Single Use Digital Flexible Ureteroscope (7.5F) is provided sterile and Package integrity and device performance testing to support a three-year shelf-life for it.

--Package validation was conducted according to ISO 11607-1:2019 and
ISO 11607 2:2019

8.0 Clinical Test Summary

No clinical study is included in this submission.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.