July 16, 2024

Zhuhai Pusen Medical Technology Co., Ltd.
Changshen Wang
Regulatory Affairs Director
5/F, Building 1, No. 33, Ke Ji San Road, High-tech zone,
TangJiaWan Town
Zhuhai, Guangdong 519000
CHINA

Re: K233778
Trade/Device Name: Single Use Suction Access Ureteroscope (PU400A, PU411A),
Single Use Flexible Video Ureteroscope (PU3033H, PU3033AH)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FED
Received: June 18, 2024

Dear Changshen 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: 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.

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.

510(k) Number *(if known)*
K233778

Device Name
Single Use Suction Access Ureteroscope (PU400A, PU411A);
Single Use Flexible Video Ureteroscope (PU3033H, PU3033AH)

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

Submitter's name: Zhuhai Pusen Medical Technology Co, Ltd.

Submitter's address: 5/F, Building 1, No 33, Keji San Road, High-tech Zone, Tangjiawan Town, 519085 Zhuhai, Guangdong, People's Republic of China.

Phone: +86 756 688 0865

Contact Person: Ellen Wang

Date Prepared: July 16, 2024

II. DEVICE

Name of Device: Pusen Single Use Flexible Video Ureteroscope (Model: PU3033H, PU3033AH) and Pusen Single Use Suction Access Ureteroscope (Model: PU400A, PU411A)

Common Name: Ureteroscope and Accessories

510(k) number: K233778

Classification Name: Ureteroscope and Accessories, Flexible/Rigid (21 CFR 876.1500)

Regulatory Class: Class II

Product Code: FGB

III. PREDICATE DEVICE

Predicate device

Name of Device: Medical Video Endoscope system

510(k) number: K172098

Classification regulation: Ureteroscope and Accessories, Flexible/rigid

Product code: FGB

This predicate device has not been subject to a design-related recall.

Reference device

Name of Device: ClearPetra Suction-Evacuation Sheath

510(k) number: K203119

Classification regulation: Endoscope and Accessories

Product code: FED, FAJ, FGA

This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Pusen Single Use Flexible Video Ureteroscope (Model: PU3033H, PU3033AH) and Pusen Single Use Suction Access Ureteroscope (Model: PU400A, PU411A) have 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. This product is for use in a hospital or qualified medical institution.

- Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope are provided sterile with the following model differences:

Product name	Single Use Suction Access Ureteroscope		Single Use Flexible Video Ureteroscope	
Model	PU400A	PU411A	PU3033H	PU3033AH
Suction access	Yes	Yes	Yes	Yes
Buttons	Yes	Yes	No	Yes

- The Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope have two LEDs and CMOS imaging sensor at its distal tip. The Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope need to be connected with the HD Medical Video Endoscope Image Processor PV300 as a system. The Pusen Single Use Flexible Video Ureteroscope and

Pusen Single Use Suction Access Ureteroscope are powered by the HD Medical Video Endoscope Image Processor PV300.

- The HD Medical Video Endoscope Image Processor PV300 was cleared under 510(k) number K222602.

V. INDICATIONS FOR USE

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.

VI. COMPARISON WITH THE PREDICATE DEVICE

a. INDICATIONS FOR USE

Item	Subject device	Predicate device	Reference device
Trade name	Single Use Flexible Video Ureteroscope Single Use Suction Access Ureteroscope	Medical Video Endoscope System	ClearPetra Suction-Evacuation Sheath
510(K) number	K233778	K172098	K203119
Indications for use	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	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.	The ClearPetra Suction-Evacuation Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment

	for irrigation and aspiration of kidney stones and stone dust during ureteral lithotripsy		of urinary stones or other urinary diseases during endoscopic procedures.

The subject device's indications for use is similar to that of the predicate device, the difference is only supplementary descriptions to the suction access functionality which aligns with that of the reference device, and this difference does not change the intended use of the subject device.

b. TECHNOLOGICAL CHARACTERISTICS

Item	Subject device	Predicate device
Trade name	Single Use Flexible Video Ureteroscope Single Use Suction Access Ureteroscope	Medical Video Endoscope System
510(K) number	K233778	K172098
Scope type	Flexible	Flexible
Scope reusability	Single-use	Single-use
Energy used	Powered by chargeable battery or line power.	Powered by chargeable battery or line power.
Digital video technology	CMOS	CMOS
Illumination source	LED	Fiber
Field of view	120 °	120 °
Direction of view	0°	0°
Depth of field	3~50 mm	3~50 mm
Maximum insertion portion width	PU3033AH, PU3033H: 2.7 mm PU400A, PU411A: 3.2	3.2 mm
Working length	PU3033AH, PU3033H: 650 mm	650 mm

	PU400A: 650 mm PU411A: 680 mm	
Working channel size	PU3033AH, PU3033H: ≥1.2 mm PU400A, PU411A: ≥5.1 Fr	1.0 mm
Up/down deflection	Up: 270° Down: 270°	Up: 270° Down: 270°
Irrigation	Provided	Provided
Suction	Provided	Not Provided
Sterility	Ethylene Oxide (EO) SAL: 10^{-6}	Ethylene Oxide (EO) SAL: 10^{-6}

The subject and the predicate device have different dimensions (e.g., working length, channel size) and illumination source. However, these differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The subject device has been verified for the safety and effectiveness based on the following performance data.

Biocompatibility testing

The biocompatibility evaluation for the Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope was conducted in accordance with the FDA final guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued on September 4, 2020) and international standard ISO 10993-1:2018 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. To support the contact classification as breached/compromised or compromised surfaces, contacting tissue for a limited duration (< 24 hours), the following endpoints were evaluated:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization
- Material-Mediated Pyrogenicity
- Acute Systemic Toxicity

The subject device passed the relevant tests and complies with ISO 10993-1.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device system, and the system complies with the IEC 60601-1 and IEC 60601-2-18 standards for safety and the IEC 60601-1-2 standard and IEC TS 60601-4-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and relevant software documentations were provided as recommended by FDA’s Guidance for Industry and FDA

staff, “Guidance for the Content of Premarket Submissions for Device Software Function” (issued on June 14, 2023).

Bench Performance Testing

Mechanical and Optical Performance

The subject device was designed to comply with applicable parts of ISO 8600.

Optical measurements and physical performances tests were performed according to applicable part of ISO 8600 standard, include appearance, working length, working channel diameter, maximum insertion width, angle of deflection, field of view and direction of view.

Mechanical characteristics were tested and include flow rate of water, suction rate and tensile strength testing.

Image quality

Comparative testing related to image quality performances were performed for the subject device and the predicate device to support substantial equivalence. The tests included color reproduction performance, optical performance (such as resolution, depth of field, image intensity uniformity, signal-to-noise ratio (SNR), dynamic range and distortion).

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.

Sterilization and shelf life

- A shelf life of 3 years for the Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope was supported with accelerated aging of final

devices, followed by simulated shipping distribution, package integrity testing, and product performance testing.

- The EO sterilization method has been validated to ISO 11135:2014.

Animal Study and Clinical study

No animal study or clinical study is included in this submission.

Summary of performance data

All tests were passed and all evaluation acceptance criteria were met.

VIII. CONCLUSIONS

The performance data described above demonstrate that the Pusen Single Use Flexible Video Ureteroscope and Pusen Single Use Suction Access Ureteroscope is as safe and effective as the predicate device and supports a substantial equivalence determination.