



April 6, 2026

Zhuhai Pusen Medical Technology Co., Ltd.  
Changshen Wang  
RA&QA Director  
# 1118, Jinrui Yi Rd., High-Tech Zone, 519085 Zhuhai, Guangdong, People' S Republic Of China  
Zhuhai, Guangdong 519085  
CHINA

Re: K260521  
Trade/Device Name: ClearEVAC Ureteral Aspirating Access Sheath  
(PUS-100-1040,PUS-100-1050, PUS-100-1240,PUS-100-1250)  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FED  
Dated: February 15, 2026  
Received: February 17, 2026

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: 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](mailto: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.

K260521

?

Please provide the device trade name(s).

?

ClearEVAC Ureteral Aspirating Access Sheath (PUS-100-1040,PUS-100-1050,  
PUS-100-1240,PUS-100-1250)

Please provide your Indications for Use below.

?

This device is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

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](#))

?

## **510(k) Summary**

### **I. SUBMITTER**

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

Submitter's Address: No. 1118, Jinrui Yi Road, High-tech Zone, Zhuhai, Guangdong 519085, PEOPLE'S REPUBLIC OF CHINA

Phone: +86 756 688 0865

Contact Person: Ellen Wang

Date Prepared: 2026-03-27

### **II. DEVICE**

Trade Name: ClearEVAC Ureteral Aspirating Access Sheath

Common Name: Ureteral Access Sheath

Classification Name: Endoscopic Access Overtube, Gastroenterology-Urology

Product Code: FED

Device Class: Class II

Regulation Name: Endoscope and Accessories

Regulation Number: 21 CFR 876.1500

### **III. PREDICATE DEVICE**

#### **Primary Predicate device**

Name of Device: Disposable Ureteral Access Sheath

510(k) number: K243710

Classification regulation: Endoscope and Accessories

Product code: FED

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

### **IV. DEVICE DESCRIPTION**

This device is a single-use ureteral sheath, EO sterilized, provided sterile. It is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is intended to be inserted into the patient's body through natural urethra.

### **V. INDICATIONS FOR USE**

This device is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.



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Patient population: It is designed for use in adults. Patients undergoing endoscopic procedures.

Use environment: This product is only for use in hospitals or qualified medical institutions.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ClearEVAC Ureteral Aspirating Access Sheath is the same / similar to the predicate devices in the following areas:

Same:

- Indications for use;
- single use;
- Anatomical site;
- EO Sterilization.

Similarities:

- Structure

Differences:

- Sheath ID;
- Sheath Length;
- Shelf life.

Description	Subject device	Predicate device	Discussion
<b>Manufacturer</b>	Zhuhai Pusen Medical Technology Co., Ltd.	Shenzhen Trious Medical Technology Co. Ltd .	N/A
<b>Product Code</b>	FED	FED	Same
<b>Classification name</b>	Endoscope and accessories	Endoscope and accessories	Same
<b>Regulation Number</b>	21 CFR § 876.1500	21 CFR § 876.1500	Same
<b>510(K) number</b>	K260521	K243710	N/A
<b>Trade name</b>	ClearEVAC Ureteral Aspirating Access Sheath	Disposable Ureteral Access Sheath	N/A
<b>Indications for use</b>	This device is used to establish	The Disposable Ureteral Access Sheath	Similar.



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Traditional 510(k)

Description	Subject device	Predicate device	Discussion
	a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.	is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.	They are all used to establish access during endoscopic procedures in the urinary tract, differing only in descriptive terminology. this difference will not raise new questions of safety and effectiveness.
<b>Regulatory Class</b>	Class II	Class II	Same
<b>Single Use</b>	Yes	Yes	Same
<b>Sterility</b>	Yes	Yes	Same
<b>Sterilization</b>	EO	EO	Same
<b>Target population</b>	Adults	Adults	Same
<b>Anatomical site</b>	Lower urinary tract.	Lower urinary tract.	Same
<b>Use Environment</b>	Hospital or qualified medical institution	Hospital environment or medical office environment.	Same
<b>Patient Contacting Materials</b>	Sheath tube: Copolyester Polyether block polyamide+Polytetrafluoroethylene  Dilator: ABS, Low density polyethylene  Sealing cap and Negative pressure valve Silicone rubber  Hydrophilic coating: PVP+PUA	Access sheath Tube body: PEBAX 6333 SA 01 MED, SUS 304, PTFE  Access sheath joint: ABS, PC (Pressure valve: ABS)  Silicone cap: silicone  Access sheath Tube body Coating: PVP	Different: The subject device ClearEVAC Ureteral Aspirating Access Sheath was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1", and it was concluded that the subject device is



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Traditional 510(k)

Description	Subject device	Predicate device	Discussion
		Dilator tube body: LDPE Dilator tube connector: HDPE	biological safe, therefore, this difference will not raise new questions of safety and effectiveness.
<b>Sheath ID</b>	10Fr ,12Fr	10Fr, 11Fr, 12Fr, 13Fr, 14Fr	Different. The predicate device is available in multiple sizes, and the inner diameter dimensions of the subject device fall within the size range of the predicate device, matching two of them exactly.  Different sheath inner diameter device will be selected by physician per patient's condition, this difference will not raise new questions of safety and effectiveness.
<b>Sheath Length</b>	40cm, 50cm	35cm, 40cm, 45cm, 50cm	Different. The predicate device is available in multiple sizes, and the sheath length dimensions of the subject device fall within the size range of the predicate device, matching two of

Description	Subject device	Predicate device	Discussion
			<p>them exactly.</p> <p>Different sheath length device will be selected by physician per patient's condition, this difference will not raise new questions of safety and effectiveness.</p>
<p><b>Primary Structure</b></p>	<p>This product consists of a guide sheath and a dilator.</p> <p>The guide sheath is composed of a sheath, a sheath hub (Y-type joint) and a sealing cap.</p> <p>The dilator has a dilator hub.</p>	<p>This product consists of access sheath and dilator tube. Z-type access sheath and T-type access sheath consist of tube body and straight joint; Y-type access sheath and W-type access sheath consist of tube body, Y-type joint and end cap; C type access sheath consists of tube body, W-type joint and end cap; the dilator tube consists of tube body and joint.</p>	<p>Similar.</p> <p>Both the subject device and predicate device consist of a guide sheath and a dilator, the subject device has a Y-type joint, the predicate device include T, C,Z and Y type connectors. The Y type of the subject device is within the range of the predicate device. This difference will not raise new questions of safety and effectiveness.</p>

Description	Subject device	Predicate device	Discussion
<b>Bending Resistance/Toughness test</b>	The tube body of the sheath and Dilator should have good toughness, and no permanent deformation should be produced when twisting 90° / 180°; After bending for 10 times and each maintained for 1 minute.(radius of curvature R=5 cm), the tube body shall not be creased or broken.	Fix the head end of the access sheath tube, dilator tube on a cylinder former with a radius of 5cm.wind the access sheath around the cylinder former for one circle ring and keep it for 1 min. Then release the wound access sheath tube. The tube body of the access sheath should remain intact without any deformations, cracks, folding, or other defective phenomena.	Similar. Added a requirement that no permanent deformation should occur when twisted 90° /180° , with no other differences. This difference will not raise new questions of safety and effectiveness.
<b>Coefficients of Friction</b>	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	Same
<b>Peak tensile force</b>	The peak tension force measured between the sheath tube and the sheath, at the locking point of the sheath tube and dilator hub, and between the dilator hub and dilator tube shall each be no less than 15 N.	The minimum peak tensile force at the access sheath tube body, and at union of the access sheath tube body and the access sheath tube joint shall not be less than 15 N.	Similar. Although the descriptions of each product component differ, the acceptance criteria for testing remain the same. This difference will not raise new questions of safety and effectiveness.
<b>Biocompatibility</b>	Cytotoxicity, Irritation, Sensitization, Acute System	Cytotoxicity, Irritation, Sensitization, Acute	Same



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Description	Subject device	Predicate device	Discussion
	Toxicity, Material mediated pyrogenicity	System Toxicity,Material mediated pyrogenicity	
<b>Shelf life</b>	2 years	3 years	<p>Different:</p> <p>A claimed shelf life of either two years or three years is a well-established and widely accepted practice in the market. Besides, the shelf life of the subject device is sufficiently validated.</p> <p>This difference will not raise new questions of safety and effectiveness.</p>

## VII. PERFORMANCE DATA

The ClearEVAC Ureteral Aspirating Access Sheath has been verified for the safety and effectiveness based on the following performance data.

### Biocompatibility testing

The biocompatibility evaluation for the ClearEVAC Ureteral Aspirating Access Sheath 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.

For the Ureteral Aspirating Access Sheath, all evaluation acceptance criteria were met.

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## **Performance Testing**

- **Bench Testing:**

Dimensions;

Surface inspection

Compatibility and Trafficability

Deformation resistance

Leakage test

Bending fatigue test

Friction coefficient

Component peak tensile force

Luer connectors

### **Animal Study and Clinical Studies (Not applicable). Other study**

- Shelf life study

- Sterilization validation

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 ClearEVAC Ureteral Aspirating Access is as safe and effective as the predicate device and supports a substantial equivalence determination.