January 30, 2025

Seplou (zhuhai) Co., Ltd.
Vince Zeng
Regulatory Affairs Manager
5th Floor, Building 1, No. 8, Keji 10th Road
Tangjiawan Town
Zhuhai, Guangddong 519086
CHINA

Re: K243025
Trade/Device Name: Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Received: January 3, 2025

Dear Vince Zeng:

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)*

K243025

Device Name

Ureteral Access Sheath (SPAS1028, SPAS1035, SPAS1045, SPAS1135, SPAS1145, SPAS1235, SPAS1245, SPAS1335, SPAS1345, SPAS1435, SPAS1445);
Ureteral Access Sheath with Suction Collection (SPAS1033S, SPAS1040S, SPAS1050S, SPAS1140S, SPAS1150S, SPAS1240S, SPAS1250S, SPAS1340S, SPAS1350S)

Indications for Use *(Describe)*

The Ureteral Access 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 of urinary stones or other urinary diseases during the endoscopic procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510k Summary

510k Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:
Date: 2025/01/03

1. Submitter (Owner) of 510k

Name: SEPLOU (ZHUHAI) CO., LTD.
Address: 5th Floor, Building 1, No. 8, Keji 10th Road, Tangjiawan Town, High-tech Zone, 519085 Zhuhai, Guangdong, People's Republic of China

2. Contact person

Vince Zeng
Regulatory Affairs Manager
Tel: +86 13650966940
Email: Vince@seplou.com

3. Subject device information

Trade Name: Ureteral Access Sheath
Common Name: Ureteral Access Sheath
Classification Name: Endoscopic Access Overtube, Gastroenterology-Urology
Regulation Number: 21 CFR 876.1500
Regulatory Classification: Class II
Product Code: FED

4. Predicate device

No	Device name	K number	Manufacturer
1	ClearPetra Suction-Evacuation Sheath	K161110	WELL LEAD MEDICAL CO., LTD.

5. Device Description

Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. The Ureteral Access Sheath provides ureteral dilation and a continuous working channel for the introduction of endoscopes and instruments during ureteral access procedures.

Ureteral Access Sheath comes in two models: Tip-unbendable Ureteral Access Sheath and Tip-bendable Ureteral Access Sheath with suction.

The Tip-unbendable Ureteral Access Sheath is offered in French size ranging from 10Fr to 14Fr and length 28cm to 45cm.

The Tip-bendable Ureteral Access Sheath with Suction is offered in French size ranging from 10Fr

to 13Fr and length 33cm to 50cm.

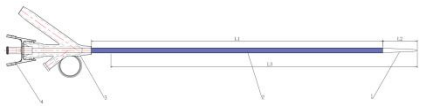
6. Intended use & Indication for use

The Ureteral Access 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 of urinary stones or other urinary diseases during the endoscopic procedures.

7. Comparison to the predicate device

The following tabulation indicates the detailed differences between the subject devices and the predicate devices.

Features	Subject Device	Pridicate Device	Remark
Product Name	Ureteral Access Sheath	ClearPetra Suction-Evacuation Sheath	/
Model Name	Ureteral Access Sheath	ClearPetra Ureteral Access Sheath	/
510k Number	Applying	K161110	/
Applicant	SEPLOU (ZHUHAI) CO., LTD.	WELL LEAD MEDICAL CO., LTD.	/
Product Code	FED	FED	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Regulatory Class	Class II	Class II	Same
Review Pannel	Gastroenterology/Urology	Gastroenterology/Urology	Same
Indications for Use	The Ureteral Access 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 of urinary stones or other urinary diseases during the endoscopic procedures.	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 designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.	Same
Patient Population	Patients undergoing endoscopic procedures, through percutaneous passages	Patients undergoing endoscopic procedures, through percutaneous passages	Same

Material	**Sheath** **Tube:**PTFE+PEBAX+304 Stainless steel Outer surface:PEBAX Inner surface:PTFE **Dilator:** LDPE	**Sheath Tube:** PTFE+PA+Stainless steel **Outer surface:** PA **Inner surface:** PTFE **Dilator:** PE	Different 1
Coating	The outer surface of the sheath has a hydrophilic coating.	The outer surface of the sheath has a hydrophilic coating.	Same
Sterilization Method	EO	EO	Same
Sheath ID	10Fr to 14Fr	10Fr to 14Fr	Same
Sheath Length	28cm to 50cm	13cm to 55cm	Different 2
Structure	1) The Tip-Unbendable Ureteral Access Sheath is comprised of Dilator, Sheath, Dilator Connector and Sheath Connector  2) The Tip-Bendable Ureteral Access Sheath with suction is comprised of Dilator, Sheath, Dilator Connector and W Connector, Straightway valve, Silicone Cap, Protective Cap 	The Ureteral Access Sheath is comprised of Sheath, Obturator, Luer Connector, Y Connector, Rubber Cap 	Different 3
Single Use	Yes	Yes	Same
Biocompatibility	Cytotoxicity, Irritation, Sensitization, Acute System Toxicity, Material mediated pyrogencity	Cytotoxicity, Irritation, Sensitization, Acute System Toxicity, Material mediated pyrogencity	Same

The subject device and predicate device have the same classification information, similar materials, same specifications, and same performance outcomes. Any differences in characteristics (material, sheath length, structure) have been supported through testing (i.e., biocompatibility testing, performance testing, and shelf-life testing). These differences do not raise different questions of safety and effectiveness.

8. Performance Data

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

determination.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity as per ISO 10993-5:2009
- Intracutaneous Irritation as per ISO 10993-10:2021
- Sensitization as per ISO 10993-21:2021
- Acute Systemic Toxicity as per ISO 10993-11:2017
- Material Mediated Pyrogenicity per ISO 10993-11:2017 and <USP 151>

Performance testing

General performance testing including:

- Dimension
- Compatibility
- Fracture Force
- Bending Resistance
- Liquid Leakage
- Surface friction coefficient

Ethylene Oxide Sterilization Validation

- ISO 11135:2014
- ISO 11737-1:2018
- ISO 11737-2:2019
- ISO 10993-7: 2008

Shelf life and Package Validation

- ISO 11607-1:2019
- DIN 58953-6
- ASTM F2096-11
- ASTM F88/F88M-15
- ASTM F1886/F1886M-16

- ASTM F1929-15
- ASTM D4169-22

Clinical study

No clinical study is included in this submission.

9. Conclusion

According to the 510(k) submission, the subject device and the predicate device have the same intended use, and the difference in technological features of the proposed devices and the predicate devices do not raise different questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed device models are substantially equivalent to the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.