September 19, 2025

Anhui Happiness Workshop Medical Instruments Co., Ltd
℅ Daguang Sun
Consultant
PureID Medical Technology Co., Ltd.
33F, Building A, Guanzhou Life Sci Innov Centre,
Guangzhou Int'l Bio Island, Huangpu District
Guangzhou,
China

Re: K250128
Trade/Device Name: Single Use Suction-Evacuation Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: August 8, 2025
Received: August 8, 2025

Dear Daguang Sun:

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 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250128

Device Name

Single Use Suction-Evacuation Ureteral Access Sheath

Indications for Use *(Describe)*

The Single Use Suction-Evacuation 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 during 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.

PureID Medical Technology Co., Ltd.
2022/08/09

510(k) Summary

Prepared on:	2025-08-05
Contact Details [21 CFR 807.92(a)(1)]	
Applicant Name	ANHUI HAPPINESS WORKSHOP MEDICAL INSTRUMENTS CO., LTD
Applicant Address	5/F, Building 4, Bengshan Science And Technology Innovation Park, 1600 Yan'an South Road, 233000 Bengbu, Anhui Province, China
Applicant Contact Telephone	(+86) 15313775083
Applicant Contact	Wang Shuanghong
Applicant Contact Email	bryant.wang@hwmeds.com
Correspondent Name	PureID Medical Technology Co., Ltd.
Correspondent Address	33F, Building A, Guanzhou Life Sci Innov Centre, Guangzhou Int'l Bio Island, Guangzhou China
Correspondent Contact Telephone	86-13776067922
Correspondent Contact	Daguang Sun
Correspondent Contact Email	raq@pureglobal.cn
Device Name [21 CFR 807.92(a)(2)]	
Device Trade Name	Single Use Suction-Evacuation Ureteral Access Sheath
Common Name	Endoscopic Access Overtube, Gastroenterology-Urology
Device Classification Name	Endoscope and Accessories
Device Classification	Class II
Regulation Number	21 CFR 876.1500
Product Code	FED
Legally Marketed Predicate Devices [21 CFR 807.92(a)(3)]	
Predicate Device 510(k) #	K161110
Predicate Trade Name (Primary Predicate is listed first)	ClearPetra Suction-Evacuation Sheath
Predicate Device Product Code	FED and 21 CFR 876.1500

Device Description Summary [21 CFR 807.92(a)(4)]

The Single Use Suction-Evacuation Ureteral Access Sheath is a single-use ureteral access sheath, which can create access to the urinary tract by provide ureteral dilation and a continuous working channel for the introduction of endoscope and instruments during ureteral access procedures. The

33F, Building A, Guanzhou Life Sci Innov Centre, Guangzhou Int'l Bio Island, Huangpu District, Guangzhou
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device can inject fluids and has vacuum pressure design which can facilitate with stone cleaning procedures.
The device consists of Dilator, Sheath, Sheath hub, Sealing cap, Dilator hub and Pressure control vent; Both dilator and sheath outer surfaces are coated with hydrophilic coatings, which provide long-lasting lubrication for better expansion and passage. The distal end of the sheath (10cm) can bend with the endoscopes, and the tip is soft which provides seamless transition between sheath core and sheath tube. The dilator and sheath are designed with radiopaque which is visible under X-Ray, can be visualized under X-ray(fluoroscopy) during placement to confirm location.

Intended Use/Indications for Use [21 CFR 807.92(a)(5)]

The Single Use Suction-Evacuation 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 during endoscopic procedures.

Technological Comparison [21 CFR 807.92(a)(6)]

There are minor differences of technological characteristic between the subject device and predicate device.

Attribute	**Subject:** **Single Use Suction-Evacuation Ureteral Access Sheath**	**Predicate:** **K161110** **ClearPetra Suction-Evacuation Sheath**
Manufacturer	ANHUI HAPPINESS WORKSHOP MEDICAL INSTRUMENTS CO., LTD	Well Lead Medical Co., LTD.
Product Code	Same	FED, FAJ, FGA
Regulation Number	Same	21 CFR§ 876.1500
Intended Use	Same	
Indications for Use	The Single-Use Suction-Evacuation Ureteral Access Sheath is intended 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 during endoscopic procedures.	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 of urinary stones or other urinary diseases during endoscopic procedures.
Mechanism of Action	Same	For the passage of endoscopes

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		and other urological devices for the purpose of performing diagnostic and surgical procedures such as, nephroscopy, ureteroscopy, or cystoscopy.
Patient Population	Same	Patients undergoing endoscopic procedures, through percutaneous passages
Patient Contacting Materials	Sheath: PVP, Pebax, SUS304, PTFE Dilator: PE	PE, PA
Sterilization	Same	EO Sterilized
Size	10, 10.5, 11, 11.5 and 12 Fr, 3.33mm, 3.5, 3.67, 3.83 and 4mm respectively	10Fr to 22Fr
OD of Obturator		Compatible with 10Fr-26Fr sheath
Length	Same	13cm to 55cm
Components	Dilator Sheath Sheath hub Sealing cap Dilator hub Pressure control vent	Sheath Obturator Connector Rubber Cap
Single Use	Same	Yes
Biocompatibility	Same	Compliance with ISO 10993-1

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92(b)]

The performance testing has been conducted on the device on the following:

- Device Performance Study including X-Ray Radiodetectability, Luer Connector and Functional testing – Passed.
- Transportation Simulation Testing per ASTM D4169 – Passed.
- Biocompatibility Study per ISO 10993 Standards – Passed.
- Sterilization Validation per USP 71 and ISO 11135 – Passed.
- Hydrophilic Coating – Passed.
- Shelf-Life per ASTM F1980 – Passed.

Conclusion

It can be concluded that, based on the obtained results from the nonclinical and clinical testing, the device is substantially equivalent to the predicate device.

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