



December 2, 2024

Hunan Vathin Medical Instrument Co., Ltd.
Jing Du
RA Manager
1/F, Building 12, Innovation Entrepreneurship Service Center
No.9 Chuanqi West Road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
CHINA

Re: K240167
Trade/Device Name: Single-use Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED

Dear Jing Du:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 8, 2024. Specifically, FDA is updating this SE Letter (incorrect predicate device manufacturer name and subject device materials table in the 510(k) Summary) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark J. Antonino, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, (240) 402-9980, Mark.Antonino@fda.hhs.gov.

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



October 8, 2024

Hunan Vathin Medical Instrument Co., Ltd.
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RA Manager
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No.9 Chuanqi West Road, Jiuhua Economic Development Zone
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Re: K240167
Trade/Device Name: Single-use Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: September 3, 2024
Received: September 4, 2024

Dear Jing Du:

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

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Enclosure

Indications for Use

510(k) Number (if known)
K240167

Device Name
Single-use Ureteral Access Sheath

Indications for Use (Describe)

The Single-use 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.

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 – K240167
Single-use Ureteral Access Sheath
Hunan Vathin Medical Instrument Co., Ltd.

I. SUBMITTER INFORMATION

Applicant: Hunan Vathin Medical Instrument Co., Ltd.
Address: 1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
Contact Person: Du Jing
Regulatory Affairs Manager
+86-18915069265
charlene@vathin.com
Date Prepared: January 19, 2024

II. SUBJECT DEVICE

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

III. PREDICATE DEVICE

Trade Name: Disposable Ureteral Access Sheath
510(k) Number: K203165
Manufacturer: Suzhou Beyo Medical Technology Co., Ltd.

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

IV. DEVICE DESCRIPTION

The Single-use Ureteral Access Sheath is a prescription device intended to provide physicians with access to the urinary tract and the capability to serve as a pathway for device exchanges.

Similar to all ureteral access sheath sets, this device also safeguards the ureter during device exchanges, thus helping to minimize tissue trauma.

The Single-use Ureteral Access Sheath consists of two components: the inner semi-rigid dilator assembly and the outer semi-rigid sheath assembly, both of which have a hydrophilic coating to allow for smooth and easy deployment into the upper tracts over a preplaced ureteral guidewire. The sheath has a locking mechanism that attaches to the luer lock hub of the inner dilator, allowing the sheath and dilator to move as a single unit.

To ease the insertion of the Single-use Ureteral Access Sheath into the body orifice, the dilator is advanced over a 0.038 inch guidewire. Since both the sheath and dilator are radiopaque, they can be monitored using X-ray (fluoroscopy) to ensure their accurate positioning during the placement process.

The Single-use Ureteral Access Sheath is designed to accommodate endoscopes and other urological instruments with an outer diameter (OD) that is compatible with the sheath's inner diameter (ID) of 10Fr, 11Fr, 12Fr, 13Fr, and 14Fr. The inner layer of the sheath is made of stainless steel to provide radial rigidity that remains patent and intact after the dilator is removed, allowing endoscopes and other urological instruments to pass easily along the lumen of the Access Sheath.

The Single-use Ureteral Access Sheath is offered in five French size combinations: 10Fr/12Fr, 11Fr/13Fr, 12Fr/14Fr, 13Fr/15Fr, and 14Fr/16Fr, and two lengths: 35cm and 45cm. The device is constructed using biologically safe materials and is provided in a sterile condition, intended for single use only.

The subject device components are made of the following materials:

Table 1. Subject Device Materials

Device Components		Contact Method	Material Full Name
Sheath	Inner Layer	Direct Contact	Austenitic stainless steel
	Outer Layer		Low-density polyethylene (LDPE)+ Thermoplastic polyurethanes (TPU)
			Polyethylene terephthalate (PET)
Sheath Hub	Hub	Indirect Contact	Polycarbonate (PC)
	Suction Nozzle		
Sheath Cap		Indirect Contact	Polycarbonate (PC)
Sealing Sleeve		Indirect Contact	Silicone
Vent Push Button		Indirect Contact	Acrylonitrile–butadiene –styrene (ABS)
Dilator		Direct Contact	Low-density polyethylene (LDPE)
Dilator Hub	Hub	Indirect Contact	Polypropylene (PP)
	Locking Clip		Polycarbonate (PC)
Hydrophilic Coatings		/	Urethane acrylate copolymer
		Direct Contact	Polyvinyl pyrrolidone (PVP)

V. INDICATIONS FOR USE

The Single-use 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Single-use Ureteral Access Sheath is like the predicate device in the following areas:

- Intended use (including application field, intended user and patient population)
- Principal operation
- Design and performance specifications
- With hydrophilic coatings
- It is single-use and delivered sterile

The following technological differences exist between the subject and predicate devices:

- The sheath hub structure
- The distal segment of the sheath can be passively bent
- It allows for suction operation
- The sheath is available in five French sizes, compared to the predicate device's three sizes
- There are two sheath lengths available, whereas the predicate device offers five lengths

The differences between the Single-use Ureteral Access Sheath and predicate device do not alter suitability of the subject device for its intended use.

Table 2. Comparison of Technological Characteristics

Description	Subject Device	Predicate Device (K203165)
Trade Name	Single-use Ureteral Access Sheath	Disposable Ureteral Access Sheath
Regulation Number	876.1500	876.1500
Regulatory Class	II	II
Product Code	FED	FED
Indications for Use	The Single-use 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 is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.
Delivered Sterile	Yes	Yes
Sterilization Method	EO	EO
Single Use	Yes	Yes
Sheath ID	10Fr, 11Fr, 12Fr, 13Fr, 14Fr	10Fr, 12Fr, 14Fr
Sheath Length	35cm, 45cm	25cm, 35cm, 40cm, 45cm, 55cm
Guidewire Compatibility	0.038" (0.97mm) guidewire can smoothly enter and exit the inner lumen of the dilator.	0.038" (0.97mm) guidewire can smoothly enter and exit the inner cavity of the dilator.

Description	Subject Device	Predicate Device (K203165)
Materials	Sheath: TPU, LDPE, PET, SUS304 Dilator: LDPE Hydrophilic coating: PVP	Sheath: PEBAX, SUS304, PTFE Dilator: LDPE Hydrophilic coating: PAM
Biocompatibility	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization
Package	Single-use EO sterilized blister box with one device per box	Single-use EO sterilized pouch with one device per pouch

VII. PERFORMANCE DATA

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

Non-Clinical Performance Data

Biocompatibility Testing

Biocompatibility of the Single-use Ureteral Access Sheath was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “breached or compromised surface” with a contact duration of “Limited (<24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity. All evaluation acceptance criteria were met.

Sterility Testing

Sterile barrier systems were evaluated in accordance with ISO 11607.

Sterilization Process has been validated accordance with ISO 11135.

Performance Testing

The following functional and mechanical performance testing were conducted on the Single-use Ureteral Access Sheath:

- Appearance
- Mark
- Size
- Luer fitting
- Patency
- Freedom from leakage

- Resistance to deformation
- Breaking force
- Connection firmness
- Toughness
- Flexural properties
- Anti-twisting force
- Compression Resistance
- Compatibility
- Air pressure Regulation Function
- Negative Pressure Suction Function
- Bending Reliability
- Corrosion resistance
- Friction
- Coating Uniformity
- Firmness
- Chemical Property

VIII. CONCLUSION

The results of the performance testing described above demonstrate the Single-use Ureteral Access Sheath is as safe and effective as the predicate device and supports a determination of substantial equivalence.