August 2, 2024

Dongguan ZSR Biomedical technology Company Limited
% Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza
West Guangzhong Road 555, Jingan District
Shanghai, 200072
CHINA

Re: K241181
Trade/Device Name: Disposable Ureteral Guide Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Received: July 15, 2024

Dear Kyra Kang:

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

K241181 - Kyra Kang

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
2024.08.02 13:46:16 -04'00'

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)*
K241181

Device Name
Disposable Ureteral Guide Sheath

Indications for Use *(Describe)*
The Disposable Ureteral Guide 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

I. Submitter

Dongguan ZSR Biomedical technology Company Limited
Unit 448, Qingfeng Road, Taihu Village, Sanzhong Village Committee, Qingxi Town,
523651 Dongguan City, Guangdong Province,PEOPLE'S REPUBLIC OF CHINA

Date of Preparation: July 25, 2024

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Submission Correspondent

Ms. Kyra Kang

Landlink Healthcare Technology (Shanghai) Co., Ltd.

E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Disposable Ureteral Guide Sheath
Common name:	Endoscope and accessories
Classification Name:	Endoscopic access overtube
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code: Review	FED
Panel:	Gastroenterology/Urology

III. Predicate Devices

	K230748
510(k) Number: Trade	Disposable Ureteral Access Sheath
name: Common	Endoscope and accessories
name: Classification:	Class II
Product Code:	FED
Manufacturer	YouCare Technology Co., Ltd.(Wuhan).

IV. Device description

The propose device, Disposable Ureteral Guide Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

This device is divided into 4 types:

- Straight type (ZSR-UA)
- Y type (ZSR-UAY)
- W type (ZSR-UAW)
- Cross type (ZSR-UAC)

The device is composed of guide sheath and dilator.The guide sheath consists of guide sheath tube and connector (straight, Y-shaped, W-shaped and cross-shaped).

The proposed devices are sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

V. Indication for use

The Disposable Ureteral Guide 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 devices

Table 1 General Comparison of Disposable Ureteral Guide Sheath

Characteristics	**Proposed device**	**Predicate device (K230748)**	**Discussion**
Manufacturer	Dongguan ZSR Biomedical technology Company Limited	YouCare Technology Co., Ltd.(Wuhan)	/
Regulation #	876.1500	876.1500	Same
Product code	FED	FED	Same
Classification name	Endoscope and accessories	Endoscope and accessories	Same
Intended use	The Disposable Ureteral Guide Sheath is used to establish a conduit during endoscopic urological procedures	The Disposable Ureteral Access Sheath is used to establish a conduit during endoscopic urological	Same

	facilitating the passage of endoscopes and other instruments into the urinary tract	procedures facilitating the passage of endoscopes and other instruments into the urinary tract	
Regulatory Class	Class II	Class II	Same
Sterility	Yes	Yes	Same
Sterilization Method	EO	EO	Same
Single Use	Yes	Yes	Same
Sheath ID	10Fr, 11Fr, 12Fr, 13Fr, 14Fr, 15Fr, 16Fr	12Fr	Different 1
Sheath length	10Fr, 11Fr, 12Fr, 13Fr, 14Fr:35cm, 40cm, 45cm, 50cm, 55cm 15Fr, 16Fr:40cm, 45cm	45cm，35cm	Different 2
Primary structure	The device is composed of guide sheath and dilator.The guide sheath consists of guide sheath tube and connector (straight, Y-shaped, W-shaped and cross-shaped).	The product is composed of sheath tube, sheath tube base, dilator and center base of dilator. The sheath tube base contains a backwater interface. The center base of dilator consists of upper cover of dilator base, lower cover of dilator base , fiber image channel interface F, irrigation channel interface I, equipment channel interface E, obturator, two-way water valve, needle free joint.	Different 3
Materials	**Sheath tube**：Pebax,SUS304,PTFE **Connector:** polyamide (PA) , silica gel **Dilator connector**：polypropylene (PP) **Dilator tube**：polyethylene (PE)	**sheath tube:**Pebax6333 SA01 MED, SUS 304、 PTFE、 PAM **sheath tube base:** ABS, PC (backwater interface: PC) **dilator**: LDPE **center base of dilator** **upper cover of the dilator**	Different 4

	Hydrophilic coating： Polyvinylpyrrolidone (PVP)	**base:** ABS **lower cover of the dilator base:** ABS **fiber image channel interface F:** PC **irrigation channel interface I:** PC **equipment channel interface E:** PC **obturator:** PC, silica gel **two-way water valve:** PC, POM **needle-free joint:** PC, silica gel	
Package	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Biocompatible	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Bending Resistance	The guiding sheath tube and the dilating tube were bent 90 ° in both directions by grasping the head and the tail. After 20 times of repetition, the tube body was free of cracks, creases, cracks and fractures, the coating was free of falling off, and the steel wire was not separated from the inner and outer rubber layers.	Bending any section of the dilator, sheath tube or the assembly of sheath tube and dilator into a ring with a radius of 5cm for 1min, there should be no crease, crack or other undesirable phenomena.	Similar 1
Coefficients of Friction	After being dipped in water, the surface is smooth, and the friction force is not more than 0.5 N; The average dynamic friction force of 25 repeated tests shall not be greater than 0.5 N	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	Similar 2
Peak tensile force	The joint between the guiding sheath tube and the tube body of the dilating tube and the connector shall be able to bear a force of ≥ 20 N and shall not break for 15 s；	The peak tensile force of the sheath tube and dilator should not be less than 15N. And the peak tensile force of the junction between sheath tube and sheath tube base, the dilator and center base of dilator also shall meet the	Similar 3

	The fracture force test shall be carried out when the guiding sheath tube connector and the expansion tube connector are locked. The minimum fracture force shall be ≥ 15N and shall not break for 15 s.	requirement.	

Different 1 – Sheath ID

This difference is in sheath ID. Different sheath inner diameter device will be selected by physician per patient's condition, this difference will not raise any issues in safety and effectiveness.

Different 2 – Sheath length

Different sheath length device will be selected by physician per patient's condition, this difference will not raise any issues in safety and effectiveness.

Different 3 – Primary structure

The predicate device has three instrument channels--- image channel, irrigation channel and equipment channel, it only increases the operation requirements for doctors. All the performance of the proposed device was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

Different 4 – Materials

Biocompatibility of the Disposable Ureteral Guide Sheath was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1", this difference will not raise any issues in safety and effectiveness.

Similar 1&2&3 – Performance

The subject device has similar performance to the predicate device. All performance of the subject device has been tested according to relevant standards and meets the requirements of the standards,this difference will not raise any issues in safety and effectiveness.

VII. Non-Clinical Testing

The device described in this summary Disposable Ureteral Guide Sheath, were

tested and demonstrated to be in conformance with the following standards:

Performance testing：

- EN 1618 Catheters otherthan intravascular catheters - Test methods for commonproperties

Biocompatibility testing

Biocompatibility of the Disposable Ureteral Guide Sheath was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1” The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic
- Pyrogenicity

Sterility and Shelf -life

- ISO 11135:2014
- ISO 11737-1:2018
- ISO11737-2:2019
- ISO 10993-7: 2008
- ASTM F1980-2016
- ASTM D3078-02-2021
- ASTMF 1929-15
- ASTM F88/F88M-15

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.