February 11, 2025

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

Re: K243155
Trade/Device Name: Single-Use Digital Flexible Ureteroscope (F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: January 3, 2025

Dear Kang Kyra:

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.

510(k) Number *(if known)*
K243155

Device Name
Single-Use Digital Flexible Ureteroscope(F-URS)(ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04)
Electronic Endoscope Imaging Processor(ZSR-EOS10)

Indications for Use *(Describe)*

Single-Use Digital Flexible Ureteroscope (F-URS)(ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04)：
This product is used in medical institutions, in conjunction with our electronic endoscope image processor, for imaging in examination, diagnosis or treatment of urinary system diseases.

Endoscope Imaging Processor (ZSR-EOS10)：
Applicable to medical institutions, which are connected with electronic endoscopes during endoscopic diagnosis and/or treatment/surgery, and effectively display images of the field of view areas of human body cavities observed by endoscopes on monitors.

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.

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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
Contact person: Mrs. Sharon Wen
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Preparation date: January 30, 2025

Submission Correspondent
Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Single-Use Digital Flexible Ureteroscope (F-URS: ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04) Electronic Endoscope Imaging Processor (ZSR-EOS10)
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code:	FGB
Review Panel:	Gastroenterology/Urology

III. Predicate Devices

510(k) Number:	K230200
Trade name:	Single-Use Flexible Ureteroscope
Common name:	Endoscope and Accessories
Classification:	Class II
Product Code:	FGB
Manufacturer	Hunan Vathin Medical Instrument Co., Ltd.

IV. Reference Devices

510(k) Number:	K221158
Trade name:	Single-Use Video Flexible Ureterorenoscope System
Common name:	Endoscope and Accessories
Classification:	Class II
Product Code:	FGB
Manufacturer	Guangzhou Red Pine Medical Instrument Co., Ltd.

V. Device description

- Single-Use Digital Flexible Ureteroscope (F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04)

  Single-Use Digital Flexible Ureteroscope (F-URS) is used in medical institutions, in conjunction with our electronic endoscope image processor, for imaging in examination, diagnosis or treatment of urinary system diseases. This device uses ethylene oxide (EO) sterilization process. This product consists of two main parts: an operating handle with directional control and connecting wires, as well as a flexible insertion tube.

- Electronic Endoscope Imaging Processor (ZSR-EOS10)

  Applicable to medical institutions, which are connected with electronic endoscopes during endoscopic diagnosis and/or treatment/surgery, and effectively display images of the field of view areas of human body cavities observed by endoscopes on monitors. The device is composed of aluminum alloy chassis and motherboard and power supply components.

The Single-Use Digital Flexible Ureteroscope (F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04) and Electronic Endoscope Imaging Processor make up the video ureteroscope system.

VI. Indication for use

Single-Use Digital Flexible Ureteroscope (F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04): This product is used in medical institutions, in conjunction with our Electronic Endoscope Imaging Processor, for imaging in examination, diagnosis or treatment of urinary system diseases.

Electronic Endoscope Imaging Processor (ZSR-EOS10): This product is used in medical institutions, in conjunction with our Single-Use Digital Flexible Ureteroscope, for imaging in examination, diagnosis or treatment of urinary system diseases.

VII. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison

Characteristics	**Proposed device**	**Predicate device (K230200)**	**Discussion**
Trade name	Single-Use Digital Flexible Ureteroscope(F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04) Electronic Endoscope Imaging Processor (ZSR-EOS10)	Single-Use Flexible Ureteroscope	/
Classification Name	Ureteroscope And Accessories, Flexible/Rigid	Ureteroscope And Accessories, Flexible/Rigid	Same
Product Code	FGB	FGB	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Indications for use	Single-Use Digital Flexible Ureteroscope (F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04): This product is used in medical institutions, in conjunction with our Electronic Endoscope Imaging Processor, for imaging in examination, diagnosis or treatment of urinary system diseases. Electronic Endoscope Imaging Processor (ZSR-EOS10): This product is used in medical institutions, in conjunction with our Single-Use Digital Flexible Ureteroscope, for imaging in examination, diagnosis or	The Single-use Flexible Ureteroscope is designed for use with Vathin Display Units, endotherapy accessories and other ancillary devices for the endoscopy and endoscopic surgery within urinary tract and kidney in adults.	Same

	treatment of urinary system diseases.		
Application field	The device is for use in a hospital or qualified medical institution.	The device is for use in a hospital or qualified medical institution.	Same
Intended user	The device is only to be used by skilled medical staff trained in clinical endoscopic techniques and procedures.	The device is only to be used by skilled medical staff trained in clinical endoscopic techniques and procedures.	Same
Patient population	Adults	Adults	Same
Scope type	Flexible	Flexible	Same
Field of view (degree)	120°±10°	110°	Same
Direction of view (degree)	0°	0°	Same
Bending angle (degree)	Up 275 °/down 275 ° (tolerance -10%, upper limit not included)	Up: 285° Down: 285°	Same
Maximum insertion portion width(mm)	ZSR-URS-01, ZSR-URS-02: 2.85 ZSR-URS-03, ZSR-URS-04: 2.50	US-S170, US-E170: 3.15 US-S180, US-E180: 3.25	Similar 1
Minimum insertion channel width(mm)	ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04: 1.2	US-S170, US-E170: 1.2 US-S180, US-E180: 1.4	Same

Working length (mm)	670mm, tolerance ± 10%	700	Same
Digital video technology	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Single-use	Yes	Yes	Same
Biocompatibility	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization	Same
Sterilization	EO	EO	Same

Analysis 1 –

Only differences in specifications and dimensions. All the performance was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

VIII.Non-Clinical Testing

The device described in this summary was tested and demonstrated to be in conformance with the following standards:

Performance testing:

- ISO16926-6:2014
- ISO 8600-5:2020
- IEC 62471:2006
- ISO 8600-1:2015
- ISO 8600-4:2014
- ISO 12233:2017
- ISO 15739:2017

- ISO/CIE 11664-4
- Wang, et al., "Development of the local magnification method for quantitative evaluation of endoscope geometric distortion." Journal of Biomedical Optics 2l, no. 5 (2016): 056003Wang et al., "Endoscope field of view measurement." Biomedical Optics Express 8, no. 3(2017):1441-1454.
- Wei-Chung Cheng, "Color Performance Review (CPR): A Color Performance Analyzer for Endoscopy Devices" in Journal of Imaging Science and Technology, 2023, pp1 -9, https://doi.org/10.2352/.ImagingSci.Technol.2023.67.5.050406

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 F88/F88M-15
- ASTM D4169-23e1

IX. Clinical Testing

No clinical study is included in this submission.

X. Conclusion

The proposed device has the same indications for use and has similar design features and technological characteristics as the predicate device. Performance testing data demonstrates that the proposed device is as safe and effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.