January 22, 2025

Hunan Endoso Life Technology Co., Ltd.
% Eric Zhang
RA manager
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan District
Shanghai, 200000
CHINA

Re: K241956
Trade/Device Name: Single-Use Digital Flexible Ureteroscope (PUR12-1, PUR12-2, PUR12-3, PUR12-4, PUR12-5, PUR12-6, PUR12-S, PUR12-S1, PUR12-S2)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: December 23, 2024
Received: December 23, 2024

Dear Eric Zhang:

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
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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)*

K241956

Device Name

Single-Use Digital Flexible Ureteroscope (PUR12-1, PUR12-2, PUR12-3, PUR12-4, PUR12-5, PUR12-6, PUR12-S, PUR12-S1, PUR12-S2)

Indications for Use *(Describe)*

As a disposable medical device, the product is used along with the company's image processor, to enter human body through the urethra and provide images via video monitor, and realize endoscopy inspection or operation to the patient's ureter and renal pelvis.

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

Date Prepared:	April 3. 18th, 2024
Manufacturer:	Hunan Endoso Life Technology Co., Ltd. 4th floor, Building 10, Innovation and Entrepreneurship Center, 31 Dongfeng Road, Heping Street, Xiangtan Economic Development District,HuNan,China 411199
Contact Person:	WangFu/RA Manager Hunan Endoso Life Technology Co., Ltd. Tel: （86）0731-52331999 Email: wangfu@endoso.com.cn
Submission Correspondent:	Mr.Eric Zhang Landlink Healthcare Technology (Shanghai) Co., Ltd. Email: eric.zhang@landlink-health.com

Identification of the Device:

Proprietary/Trade Name:	Single-Use Digital Flexible Ureteroscope
Model:	PUR12-1, PUR12-2, PUR12-3, PUR12-4, PUR12-5, PUR12-6, PUR12-S, PUR12-S1, PUR12-S2
Common Name:	Ureteroscope and accessories, flexible/rigid
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FGB
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Device:

510(k) Number :	K230200
Trade name :	Single-Use Flexible Ureteroscope
Classification Name:	Endoscope and accessories
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FGB
Device Class:	Class II

Device Description:

The Single-Use Digital Flexible Ureteroscope (Model: PUR12-1, PUR12-2, PUR12-3, PUR12-4, PUR12-5, PUR12-6, PUR12-S, PUR12-S1, PUR12-S2) is an endoscope which is used with the Monitor for Single-Use Endoscopy (Model:P1-D) produced by ENDOSO LIFE TECHNOLOGY for providing endoscopic imaging of the ureter and

the renal pelvis for the purpose of diagnosis and treatment. The Single-Use Digital Flexible Ureteroscope is integrated with a working channel which allowing the use of flexible endoscopic accessories (e.g. stone basket, forceps, laser fibers for lithotripsy, etc.). The insertion portion of the endoscope is flexible, and the shape changes corresponding to the shape of the cavity. Anatomical images are captured by a CMOS chip at the distal end of the endoscope and the electronic signals are transmitted to the Monitor. Then, the resulting picture images are sent to and shown on a visual display.
Mechanism of action:
The light emitted by the LED cold light source at the distal tip of the disposable Single-Use Digital Flexible Ureteroscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the Monitor via the VI circuit. The Monitor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the attached monitor. The Monitor also controls the brightness of the LEDs on the endoscope.

Single-Use Digital Flexible Ureteroscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

Indications for Use:
As a disposable medical device, the product is used along with the company's image processor, to enter human body through the urethra and provide images via video monitor, and realize endoscopy inspection or operation to the patient's ureter and renal pelvis.

Comparison with Predicate Device:
The Single-Use Digital Flexible Ureteroscope and its predicate device, Hunan Vathin Medical Instrument Co., Ltd. (K230200) have the same intended use, sterilization Methods and similar physical characteristics, optical characteristics.

Substantial Equivalence:
The Single-Use Digital Flexible Ureteroscope employs the same fundamental scientific technology as its predicate devices, as below table:

	Subject Device	Predicate Device K230200	Comparison
Trade Name	Single-Use Digital Flexible Ureteroscope	Single-Use Flexible Ureteroscope	/
Classification Name	Endoscope and accessories	Endoscope and accessories	/
Product Code	FGB	FGB	/
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	/
Indications for use	As a disposable medical device, the product is used along with the company's image processor, to enter human body through the urethra and provide images via video monitor, and realize endoscopy inspection or operation to the patient's ureter and renal pelvis.	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
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	Use in a Healthcare facility/hospital environment by trained surgical physicians who are familiar with endoscopic 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

	Subject Device	Predicate Device K230200	Comparison
Field of view (degree)	120°±10%	110°	Similar 1
Direction of view (degree)	0°	0°	Same
Bending angle (degree)	260°~300°	Up: 285° Down: 285°	Similar 2
Maximum insertion portion width(mm)	≤2.6mm (7.7Fr)	3.15	Similar 3
Minimum insertion channel width(mm)	1.2	1.2	Same
Working length (mm)	670±3%	700	Similar 4
Working length (mm)	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Single-use	Yes	Yes	Same
Sterilization	EO	EO	Same

Analysis of similar1:
The Field of View of the subject device is similar as the predicate device.The optical performance of the subject device was tested and the results met the ISO 8600 series, this difference will not raise any issues in safety and effectiveness.

Analysis of similar 2:
The Bending angle (degree) of the subject device is similar as the predicate device.All the performance was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

Analysis of similar 3:

The Maximum insertion portion width(mm of the subject device is thinner than the predicate device. All the performance was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

Analysis of similar 4:
The Working length (mm) of the subject device is similar as the predicate device.All the performance was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions
The Single-Use Digital Flexible Ureteroscope was designed to comply with applicable parts of ISO 8600. Optical measurements were performed according to applicable part of ISO 8600 standard.
Mechanical characteristics were tested and include leakage tightness, bending, deflection endurance, withstand of channel. Photobilogical safety of lamps test according to IEC 62471.

In addition, comparative testing related to image quality parameters including Color performance (color reproduction), optical performance (resolution, depth of field and image intensity uniformity, distortion), and dynamic range test was performed for submitted Single-Use Digital Flexible Ureteroscope and the predicate device to support substantial equivalence.
In addition to above, subject device has also performed following non-clinical performances testing:

Biocompatibility
The biocompatibility evaluation for the patient contacting components of the Single-Use Digital Flexible Ureteroscope was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted based contact category of "Surface-Breached or compromised surface" with a contact duration of "Limited (< 24 hours):
• Cytotoxicity: ISO 10993-5:2009/(R) 2014
• Sensitization, Intracutaneous reactivity/irritation: ISO 10993-10:2010
• Material-mediated pyrogenicity: ISO 10993-11:2017
• Acute systemic toxicity: ISO 10993-11:2017

Sterilization and sterile testing
The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life of the Single-Use Digital Flexible Ureteroscope is determined based on stability study which includes ageing test according to ASTM F1980-16, Standard

Guide for Accelerated Aging of Sterile Barrier.Both product performance and sterile testing were tested after aging test.

Package integrity testing

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and F88/F88M-15, ASTM F 1929-15.

Transport and shipping testing as per ASTM D4169-16.Package integrity testing was performed after aging testing.

Electrical Safety and EMC

The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:

•ANSI/AAMI ES:60601-1:2005/A2:2010

•IEC 60601-2-18:2009

•IEC 60601-1-2:2014

Clinical Tests:

The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Single-Use Digital Flexible Ureteroscope is substantially equivalent to the predicate device.