October 4, 2024

Shenzhen Besdata Technology Co., Ltd.
Xiaohong Lu
General Manager
503, Building #2, Xinnantian Industrial Park, No. 3179
Laokeng Community, Longtian Street, Pingshan District
Shenzhen, Guangdong 518128
CHINA

Re: K240074
Trade/Device Name: Single use flexible ureteroscope (UR-D1);
Single use flexible ureteroscope (UR-D2);
Single use flexible ureteroscope (UR-F1);
Single use flexible ureteroscope (UR-F2)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: September 4, 2024
Received: September 4, 2024

Dear Xiaohong Lu:

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
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)*

K240074

Device Name

Single use flexible ureteroscope (UR-D1/UR-D2/UR-F1/UR-F2);
Image processor (MIP1001/MIP1002)

Indications for Use *(Describe)*

The Single use flexible ureteroscope has been designed to be used with Endo-Therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

The Image processor is used in conjunction with the video endoscopes produced by BESDATA to process the images collected by the video endoscopes and send it to the display, and provide power for the endoscope.

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.

510(k) SUMMARY

510(k) Number: K240074

I.SUBMITTER

Name: Shenzhen Besdata Technology Co,Ltd.

Address: 503, Building #2, Xinnantian Industrial Park, No. 3179, Danzi Avenue, Laokeng Community, Longtian Street, Pingshan District, Shenzhen

Name of contact person: Xiaohong Lu

Tel: +86 755 84416070

Fax: +86 755 23039200

E-mail: regulation@besdatatech.com

Date prepared: October 2, 2024

II. Proposed Device

Submission Number: K240074

Trade/Device name: Single use flexible ureteroscope system

Regulation number: 21CFR 876.1500

Classification Name: Ureteroscope and accessories, flexible/rigid

Regulation class: II

Review Panel: Gastroenterology/Urology

Product code: FGB

Common Name: Ureteroscope and accessories

III. Predicate Device

510(k) Number: K172098
Trade/Device Name: Medical Video Endoscope System

Applicant: Zhuhai Pusen Medical Technology Co, Ltd.

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulation class: II

Review Panel: Gastroenterology/Urology

Product code: FGB

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

IV.Reference Device

510(k) Number: K210579

Device name: WiScope® OM Endoscope System

Applicant: OTU Medical Inc.

Regulation number:21 CFR 876.1500

Common/Usual Name: Endoscope and Accessories

Regulation class: II

Review Panel: Gastroenterology/Urology

Product code: FBN, FGB

Note: This reference device has not been subject to a design-related recall.

V. Indications for use

Single use flexible ureteroscope has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

The image processor is used in conjunction with the video endoscopes produced by BESDATA to process the images collected by the video endoscopes and send it to the display, and provide power for the endoscope.

VI. Description of the Device

The Single use flexible ureteroscope system consists of a sterile Single use flexible ureteroscope and an Image processor.

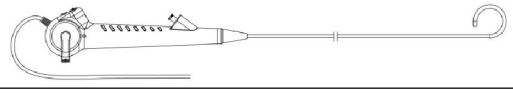
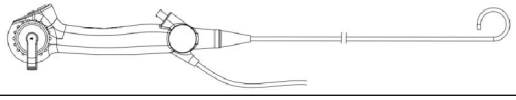
➢Description of the ureteroscope

Name： Single use flexible ureteroscope

Model: UR-D1, UR-D2, UR-F1, UR-F2

There are four models of the Single use flexible ureteroscope. Different models are the same except for size and handle appearance. The ' D ' and ' F ' indicate that the appearance of different handles is different, ' 1 ' and ' 2 'represent different Maximum widths of insulation portion.

As shown in the table below:

Model	Maximum widths of insulation portion	handle appearance
UR-D1	2.8mm	
UR-D2	2.5mm	
UR-F1	2.8mm	
UR-F2	2.5mm	

The only difference in the appearance of the handle is to cater to the grip habits of different doctors.

Single use flexible ureteroscope is a sterile product for single use, and repeated use is prohibited.The Single use flexible ureteroscope is a portable equipment. The Single use flexible ureteroscope mainly consists of the distal, insertion portion, handle,connection cable and LEMO plug:

1)The distal including LED lighting, optical lens, CMOS imaging module.

2) The insertion portion includes the instrument channel and insertion tube.

3) The handle includes instrument channel ports, hand push rods, imaging control button switches and connecting the cable (with LEMO plug).

Single use flexible ureteroscope is connected to the image processor through the LEMO plug on the connecting cable, and the patient's area is illuminated and imaged by the LED and camera of the insertion tube Distal. The CMOS sensor of the insertion tube Distal collects optical signals in imaging and converts them into electrical signals, which are transmitted to the image processor for display. There is an instrument channel in the insertion tube for operating diagnostic and therapeutic accessories (not configured on this device) through the instrument channel. The instrument channel can also provide water/air supply facilities for water/air supply through the instrument channel. Water supply is used to remove mucus attached to the surface of the camera, while air supply is used to remove residual water droplets on the surface of the camera. The handles each have two imaging button, and a push rod. The imaging button can control imaging (One button controls taking photos and one button controls recording), and the push rod can control the curvature of the insertion tube Distal.

The materials used in construction of the insertion portion of ureteroscope are Polytetrafluoroethylene (PTFE), Polyether-polyamide block copolymers (PEBAX), and polycarbonate (PC). The insertion portion is considered to contact a breached or compromised surface for a duration of less than 24 hours. The biocompatibility evaluation was conducted in accordance with the FDA guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’” and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

The handle does not contact the patient.

➢**Description of the Image processor**

Name：Image processor

Model: MIP1001, MIP1002

The model MIP1001 and MIP1002 were identical except for position of button and different appearance size. As shown in the table below:

Model	Size	position of button
MIP1001	259 mm x 206 mm x 50 mm	The button is located at the top of the device
MIP1002	252 mm x 278 mm x 55 mm	The button is located at the bottom of the device

Image processor is a lightweight endoscope video display, This device is composed of image processor, power adapter(power supply), LCD screen(image display) and image processing motherboard(function).

The endoscopic video image processor can process the image collected by the endoscope and display the image in real time through the LCD module. Users can use the LCD module for humanmachine interaction.

The principle of optical imaging: the light source illuminates the inspected site of the patient, which is imaged by the photosensitive surface of endoscope's CMOS camera module. The optical signal received by the CMOS sensor is converted into electrical signal after processing. The electrical signal is then transmitted by the cable to the signal processing chip embedded on the Image processor where it is restored after processing and finally displayed on the screen of Image processor.

VIII.Comparison with the Predicate Devices

➢Comparison of Indications with the Predicate Devices

Regarding the indications for use, although the subject device lacks integrated biopsy functionality compared to the predicate device, the intended use of both of them are the same.

➢Comparison of Technological Characteristics with the Predicate Devices

Subjective device and the predicate device have the same intended use. The subject and predicate device have similar technological characteristics as evidenced by the table below. All differences have been discussed in detail and concluded that these differences in technological characteristics do not raise new questions regarding safety or effectiveness of the subject device.

a. The following basic technological elements are the same or similar for the subject and predicate devices :

Table 1 General Comparison

Item	Proposed Device	Predicate Device	Reference Device	Remark
	Single use flexible ureteroscope	**Pusen Single Use Flexible Video Ureteroscope**	**WiScope® OM Endoscope System**	
510(k) number	**K240073**	**K172098**	**K210579**	
Product Code	FGB	FGB	FBN, FGB	Same
Regulation Number	21CFR 876.1500	21CFR 876.1500	21CFR 876.1500	Same
Indications for Use	Single use flexible ureteroscope has been designed to be used with endo therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.	This instrument has been designed to be used with endo therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.	WiScope® OM Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. WiScope® OM Endoscope System is also intended to be used by physicians through percutaneous insertion to access, visualize, and	Note1

Item	Proposed Device Single use flexible ureteroscope	Predicate Device Pusen Single Use Flexible Video Ureteroscope	Reference Device WiScope® OM Endoscope System	Remark
510(k) number	**K240073**	**K172098**	**K210579**	
			perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	
Patient Population	Adult	Adult	Adult	Same
where used	Hospitals	Hospitals	Hospitals	Same

Table 2 Performance Comparison

Item	Proposed Device	Predicate Device	Reference Device	Remark
	Single use flexible ureteroscope	Pusen Single Use Flexible Video Ureteroscope	WiScope® OM Endoscope System	
510(k) number	K240073	K172098	K210579	
Digital video technology	CMOS	CMOS	CMOS	Same
Light source	LED	LED	LED	Same
Field of view(degree)	120°	120°	100°	Same as the Predicate Device
Direction of view(degree)	0°	0°	0°	Same
Resolution ratio	400×400	Unknow	16.0 million pixels	Note 2
Depth of field	3-50mm	3-50mm	2-50mm	Same as the Predicate Device
Instrument channel width	UR-D1: Φ1.2mm UR-D2: Φ1.2mm UR-F1: Φ1.2mm UR-F2: Φ1.2mm	1.0 mm	3.6Fr	Note 3
Maximum width of insertion tube	UR-D1: Φ2.8mm UR-D2: Φ2.5mm UR-F1: Φ2.8mm UR-F2: Φ2.5mm	3.2 mm	8.6Fr	Note 4
Working length of the	650mm	650 mm	670mm	Same as the Reference Device

Item	Proposed Device Single use flexible ureteroscope	Predicate Device Pusen Single Use Flexible Video Ureteroscope	Reference Device WiScope® OM Endoscope System	Remark
510(k) number	**K240073**	**K172098**	**K210579**	
insertion section				
Bending angle(degree)	Upper: 275° Down: 275°	Upper: 270° Down: 270°	Upper: 275° Down: 275°	Same as the Reference Device
Ureteroscope	Single-Use	Single-Use	Single-Use	Same
Sterilization	EO SAL: 10-6	EO SAL: 10-6	EO SAL: 10-6	Same
White balance	Yes	Yes	Yes	Same
Brightness Control	Yes	Yes	Yes	Same

b. Discussion on differences between the subject and the predicate device

. Note 1 Indications for Use	Regarding the indications for use, compared to the predicate device, the intended use of both of them are the same. The intended use of the subject device is the same as that of the reference device in the urinary tract and the kidney, with only slight differences in description. The indications of reference device contain two aspects, to performing various diagnostic and therapeutic procedures within the urinary tract (code “FGB”) and to examining and performing procedures within the bile ducts. (code “FBN”). The aspect compared with the proposed device is to performing various diagnostic and therapeutic procedures

	within the urinary tract (code “FGB”). The indications which represented by code “FBN” are not in the scope of comparison. So the product codes and the indications of use can be judged as equal.
Note 2 Resolution ratio	Same as the refence Device. The different with Predicate Device does not adversely impact safety and effectiveness of proposed device.
Note 3 Instrument channel width	The instrument channel width of the subject device is the same as the reference device, but larger than the predicate device. The larger the indicator, the more advantageous it is for clinical application. Therefore, the different does not adversely impact safety and effectiveness of subject device.
Note 4 Maximum width of insertion tube	The Maximum width of insertion tube of the subject device is smaller than the predicate devices, The smaller of the Maximum width of insertion tube, the more advantageous it is for clinical application. Therefore, the different does not adversely impact safety and effectiveness of subject device.The subject device offers a variety of sizes for flexible selection.

IX.Summary of Non-clinical Performance

All non-clinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate device and reference device. Tests setup and execution were performed in accordance with applicable standards. Results of the testing demonstrate compliance to the standards and matching the performance of subject device to the reference device. The following performance data were provided in support of the substantial equivalence determination.

- **Biocompatibility**

The biocompatibility evaluation for the Single use flexible ureteroscope was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The insertion portion of Single use flexible ureteroscope is considered to contact a breached or compromised surface for a duration of less than 24 hours; therefore, the following tests are considered and passed:

Biocompatibility testing summary	
Test	**Testing Summary**
Cytotoxicity test (ISO 10993-5:2009 "Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity)	No Cytotoxicity
Skin sensitization test (ISO 10993-10:2010 "Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization)	No evidence of skin sensitization
Vaginal irritation Test (ISO 10993-23:2021 Biological evaluation of medical devices-Part 10: Tests for irritation and vaginal irritation)	No evidence of irritation
Acute Systemic Toxicity Test(ISO 10993-11:2017 "Biological evaluation of medical devices – Part 11: Tests for systemic toxicity")	No evidence of Acute Systemic Toxicity

Pyrogen Test(ISO 10993-11:2017 “Biological evaluation of medical devices – Part 11: Tests for systemic toxicity”)	No evidence of Pyrogen

- **Electrical Safety and Electromagnetic Compatibility**

Electrical safety and EMC testing were conducted on the Single use flexible ureteroscope and image processor, and the device complies with the following standards:

• IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

• IEC 60601-2-18: 2009 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment.

• IEC 60601-1-2: 2014 + A1: 2020 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests.

• IEC TR 60601-4-2:2016 Medical electrical equipment- Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

- **Photobiological safety**

The subject device was tested according to the following FDA recognized standards:

• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems.

- **Sterilization Validation**

The EO sterilization of the Single use flexible ureteroscope has been validated according to the following applicable standards:

• ISO11135:2014: Sterilization of medical device- validation and routine control of ethylene oxide sterilization

• ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods part 2: Tests of sterility performed in the validation of a sterilization process

• ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

• USP <85> Bacterial endotoxins test

- **Shelf Life and Sterile Barrier System (Packaging)**

Shelf Life and Sterile Barrier System of the Single use flexible ureteroscope has been validated according to the following applicable standards:

• ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

• ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

• ISO11607-1:2020 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials, sterile barrier systems and packaging systems

• ISO11607-2:2020 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process

• ASTM F 1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

• ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

• DIN 58953-6:2016 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized

• ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

• ASTM F1608-16 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)

- **Performance Data – Bench**

The following performance data were provided in support of the substantial equivalence, as shown in the table below.

The optical performance testing was conducted in accordance with applicable parts of ISO 8600-1:2015, ISO 8600-3:2019, ISO 12233-2017, ISO15739-2017 and ISO/CIE 11664-4 standards, and the mechanical performance testing was conducted in accordance with applicable parts of ISO 8600-1:2015, ISO 8600-4:2014, YY/T 1028- 2023 standards. The field of view was measured according to the test method in the article: Wang et al.,

"Endoscope field of view measurement." Biomedical Optics Express 8, no. 3 (2017): 1441-1454, and geometric distortion was measured according to section 3 of the article: Wang, et al., "Development of the local magnification method for quantitative evaluation of endoscope geometric distortion." Journal of Biomedical Optics 21, no. 5 (2016): 056003.

Test category	Test item
Optical performance	Resolution
	Direction of view
	Depth of Field
	Field of view
	Geometric Distortion
	Signal-To-Noise Ratio
	Dynamic Range
	Image Intensity Uniformity (IIU)
	Color Performance
Mechanical performance	Basic Size
	Bending angle(degree)

- **Performance Data – Animal**

N/A, no animal studies are available for the subject device.

X.Clinical Evidence

N/A.

XI.Conclusion

In conclusion, the technological characteristics, features, specifications, and intended use of the subject device are substantially equivalent to the predicate device quoted above. The differences between the subjective device and the predicate device do not raise new questions of safety and effectiveness. Performance testing demonstrated that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.