September 26, 2022

Zhuhai Pusen Medical Technology Co., Ltd.
Changshen Wang
Regulatory Affairs Director
5/F, Building 1, No 33, Ke Ji San Road
High-tech Zone, Tangjiawan Town
Zhuhai, Guangdong 519085
China

Re: K222602
Trade/Device Name: Pusen Single Use Flexible Video Cystoscope System (Single Use Flexible Video Cystoscope: PC200-AS, PC200-AR, PC200-S and PC200-R; HD Medical Video Endoscope Image Processor: PV300)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: August 25, 2022
Received: August 29, 2022

Dear Changshen Wang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222602

Device Name
Pusen Single Use Flexible Video Cystoscope System (Single Use Flexible Video Cystoscope: PC200-AS, PC200-AR, PC200-S and PC200-R; HD Medical Video Endoscope Image Processor: PV300)

Indications for Use *(Describe)*
The Pusen Single Use Flexible Video Cystoscope System is intended to be used for endoscopic access to and examination of the lower urinary tract. The Pusen Single Use Flexible Video Cystoscope is intended to provide visualization via video processor and can be used with endoscopic accessories. This system is intended for use in a hospital environment or medical office environment.

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

Submitter's name: Zhuhai Pusen Medical Technology Co, Ltd.
Submitter's address: 5/F, Building 1, No 33, Keji San Road, High-tech Zone, Tangjiawan Town, 519085 Zhuhai, Guangdong, People's Republic of China.

Phone: +86 756 688 0865

Contact Person: Ellen Wang
Date Prepared: September 22, 2022

II. DEVICE

Name of Device: Pusen Single Use Flexible Video Cystoscope System (Single Use Flexible Video Cystoscope: PC200-AS, PC200-AR, PC200-S and PC200-R; HD Medical Video Endoscope Image Processor: PV300)
Common Name: Cystoscope and accessories
510(k) number: K222602
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: Class II
Product Code: FAJ

III. PREDICATE DEVICE

Predicate device
Name of Device: Ambu aScope 4 Cysto
510(k) number: K193095
Classification regulation: Cystoscope and Accessories, Flexible/Rigid
Product code: FAJ
This predicate device has not been subject to a design-related recall.

Reference device
Name of Device: EVIS EXERA II 180 SYSTEM
510(k) number: K133538
Classification regulation: Endoscope and Accessories
Product code: NWB; FAJ
This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Pusen Single Use Flexible Video Cystoscope System includes a Single Use Flexible Video Cystoscope and an HD Medical Video Endoscope Image Processor.

The system is intended to be used by physicians for endoscopic access to and examination of the lower urinary tract in adults. This system is intended to provide visualization and can be used with endoscopic accessories. This system is intended for use in a hospital environment or medical office environment.

- The Pusen Single Use Flexible Video Cystoscope is provided sterile and has the following 4 models:

Model	Description of difference
PC200-AS	'A' means this model has function buttons; 'S' means standard deflection.
PC200-AR	'A' means this model has function buttons; 'R' means reverse deflection.
PC200-S	'S' means standard deflection.
PC200-R	'R' means reverse deflection.

- The Pusen Single Use Flexible Video Cystoscope has two LEDs and CMOS imaging sensor at its distal tip. The Pusen Single Use Flexible Video Cystoscope needs to be connected with the HD Medical Video Endoscope Image Processor PV300 as a system. The Pusen Single Use Flexible Video Cystoscope is powered by the HD Medical Video Endoscope Image Processor PV300.
- The HD Medical Video Endoscope Image Processor PV300 is a reusable device, used to process the image signal from the Pusen Single Use Flexible Video Cystoscope and display the real-time video on its LCD screen, which enables visual examination of the lower urinary tract (the urethra and the bladder).

V. INDICATIONS FOR USE

The subject device: The Pusen Single Use Flexible Video Cystoscope System is intended to be used for endoscopic access to and examination of the lower urinary tract. The Pusen Single Use Flexible Video Cystoscope is intended to provide visualization via video processor and can be used with endoscopic accessories. This system is intended for use in a hospital environment or medical office environment.

The predicate device: Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories. Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment. Ambu® aScope™ 4 Cysto is designed for use in adults.

The indications for use are the same for the subject device and the predicate device. The subject and predicate device have the same intended use – to provide visualization in the lower urinary tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Subject device	Predicate device
Trade name	Pusen Single Use Flexible Video Cystoscope System	Ambu aScope 4 Cysto
510(K) number	K222602	K193095
Scope type	Flexible	Flexible
Scope reusability	Single-use	Single-use
Energy used	Powered by chargeable battery or line power.	Powered by chargeable battery or line power.
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Field of view	90 °	120 °
Direction of view	30°	0°
Depth of field	3~80 mm	5~50mm
Maximum insertion portion width	18 Fr	18 Fr
Working length	380 mm	390 mm
Working channel size	2.3 mm	2.2 mm
Up/down deflection	Up: 210° Down: 210°	Up: 210° Down: 120°
Suction	Provided	Not Provided
Sterility	Ethylene Oxide (EO) SAL: 10^{-6}	EO SAL: 10^{-6}

The subject and the predicate device have different dimensions (e.g., working length, channel size) and optical specifications (e.g., depth of field, field of view, direction of view). However, these differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The subject device has been verified for the safety and effectiveness based on the following performance data.

Biocompatibility testing

The biocompatibility evaluation for the Pusen Single Use Flexible Video Cystoscope was conducted in accordance with the FDA final guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" (issued on September 4, 2020) and international standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. To support the contact classification as a surface device contacting mucosal membrane for a limited duration, the following endpoints were evaluated:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization

The subject device passed the relevant tests and complies with ISO 10993-1.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device system, and the system complies with the IEC 60601-1 and IEC 60601-2-18 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and relevant software documentations were provided as recommended by FDA's Guidance for Industry and FDA staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Bench Performance Testing

Mechanical and Optical Performance

The subject device was designed to comply with applicable parts of ISO 8600. Optical measurements and physical performances tests were performed according to applicable part of ISO 8600 standard, include appearance, working length, working channel diameter, maximum insertion width, angle of deflection, field of view and direction of view.
Mechanical characteristics were tested and include flow rate of water, suction rate and tensile strength testing.

Image quality

Comparative testing related to image quality performances including color performance (color reproduction and color contrast enhancement), optical performance (resolution, depth of field, image intensity uniformity and distortion) tests were performed for the subject device and the predicate device to support substantial equivalence.

Photobiological safety

The LEDs in the subject device were tested according to the following FDA recognized standards:
• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems.

Luer taper

Luer taper in the subject device was tested according to ISO 80369-7: 2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.

Sterilization and shelf life

- A shelf life of 3 years for the Pusen Single Use Flexible Video Cystoscope was supported with accelerated aging of final finished devices, followed by simulated shipping distribution, package integrity testing, and product performance testing.
- The EO sterilization method has been validated to ISO 11135:2014. (only applicable to the Pusen Single Use Flexible Video Cystoscope)
- Reprocessing method was validated in accordance with the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”. (only applicable to the HD Medical Video Endoscope Image Processor)

Animal Study and Clinical study

No animal study or clinical study is included in this submission.

Summary of performance data

All tests were passed and all evaluation acceptance criteria were met.

VIII. CONCLUSIONS

The performance data described above demonstrate that the Pusen Single Use Flexible Video Cystoscope System is as safe and effective as the predicate device and supports a substantial equivalence determination.