June 22, 2023

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: K223741
Trade/Device Name: Pusen Single Use Flexible Video Cystoscope/Choledochoscope System (Single Use Flexible Video Cystoscope/Choledochoscope: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: FBN, FAJ
Dated: December 12, 2022
Received: May 18, 2023

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223741

Device Name
Pusen Single Use Flexible Video Cystoscope/Choledochoscope System (Single Use Flexible Video Cystoscope/Choledochoscope: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/Choledochoscope System is intended to be used for endoscopic access to and examination of the lower urinary tract. This system is also indicated for the examination and therapeutic applications during endoscopic procedures in bile ducts. The Cystoscope/Choledochoscope 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.

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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: May 16, 2023

II. DEVICE

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

III. PREDICATE DEVICE

Predicate device
Name of Device: Flexible Video-Choledo-Cysto-Ureteroscope System
510(k) number: K211686
Classification Name: Endoscope and Accessories
Product code: FGB, FBN, FET, FAJ, FGA
This predicate device has not been subject to a design-related recall.

Reference device
Name of Device: Pusen Single Use Flexible Video Cystoscope System
510(k) number: K222602
Classification regulation: Endoscope and Accessories
Product code: FAJ
This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

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

This system is intended to be used for endoscopic access to and examination of the lower urinary tract. This system is also indicated for the examination and therapeutic applications during endoscopic procedures in bile ducts. This Cystoscope/Choledochoscope 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 Pusen Single Use Flexible Video Cystoscope/Choledochoscope 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/Choledochoscope needs to be connected with the HD Medical Video Endoscope Image Processor PV300 as a system, and it is powered by the latter.
- 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/Choledochoscope and display the real-time video on its LCD screen, which enables visual examination of target site.

This change is to expand the indications for the currently cleared reference Pusen Single Use Flexible Video Cystoscope System (K222602) to allow it to also be marketed as a Choledochoscope used for examination and therapeutic applications during endoscopic procedures in bile ducts. No changes were made to the device design. Only the product name, indications for use and applicable labeling were updated.

V. INDICATIONS FOR USE

The subject device: The Pusen Single Use Flexible Video Cystoscope/Choledochoscope System is intended to be used for endoscopic access to and examination of the lower urinary tract. This system is also indicated for the examination and therapeutic applications during endoscopic procedures in bile ducts. This Cystoscope/Choledochoscope 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: The Flexible Video-Choledo-Cysto-Ureteroscope System is indicated for endoscopic examination in the urinary tract and can be used percutaneously to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The Flexible Video-Choledo-Cysto-Ureteroscope System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

The indications for use of the subject device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Subject device	Predicate device	Reference device
Trade name	Pusen Single Use Flexible Video Cystoscope/Choledochoscope System	Flexible Video-Choledo-Cysto-Ureteroscope System	Pusen Single Use Flexible Video Cystoscope System
510(K) number	N/A	K211686	K222602
Scope type	Flexible	Flexible	Flexible
Scope reusability	Single-use	Single-use	Single-use
Energy used	Powered by chargeable battery or line power.	Powered by chargeable battery or line power.	Powered by chargeable battery or line power.
Digital video technology	CMOS	CMOS	CMOS
Illumination source	LED	LED	LED
Field of view	90 °	110 °	90 °
Direction of view	0°	0°	30°
Depth of field	3~80 mm	5~50mm	3~80 mm
Maximum insertion portion width	5.6mm	5.3mm	6.0mm
Working length	380 mm	385 mm	380 mm

Working channel size	2.3 mm	2.6 mm	2.3 mm
Up/down deflection	Up: 210° Down: 210°	Up: 210° Down: 130°	Up: 210° Down: 210°
Suction	Provided	Not Provided	Provided
Sterility	Ethylene Oxide (EO) SAL: 10^{-6}	EO SAL: 10^{-6}	Ethylene Oxide (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). However, these differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Non-Clinical Performance Data

The Pusen Single Use Flexible Video Cystoscope/Choledochoscope System and reference Pusen Single Use Flexible Video Cystoscope System (K222602) share the same fundamental technology and physical characteristics except for the Direction of view and the Maximum insertion portion width, verification reports on these two performances are provided. The other performance data described in the cleared Pusen Single Use Flexible Video Cystoscope System, K222602, is also applicable to the Pusen Single Use Flexible Video Cystoscope/Choledochoscope System. The labelling was updated to reflect the new indications and new specifications.

Animal Study and Clinical study

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

VIII. CONCLUSIONS

The Pusen Single Use Flexible Video Cystoscope/Choledochoscope System is substantially equivalent to its predicate device. Performance testing and compliance with voluntary standards, demonstrate that the subject device is substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use. Therefore, the subject devices are determined to be substantially equivalent to the referenced predicate devices.