October 17, 2023

Shanghai AnQing Medical Instrument Co., Ltd
Shuwen Fan
RA Manager
3 & 4 Floor, No.2 Building, 366 Huiqing Rd
East Zhangjiang High-Tech Park
Shanghai, 201201
China

Re: K231105
Trade/Device Name: Flexible Choledochoscope (Model: CS50H-20EU, CS50H-20US)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN
Dated: September 15, 2023
Received: September 15, 2023

Dear Shuwen Fan:

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.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant 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)*
K231105

Device Name
Flexible Choledochoscope (Model: CS50H-20EU, CS50H-20US)

Indications for Use *(Describe)*
AnQing Medical Flexible Choledochoscope has been designed to be used with the video processor, monitor, endotherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct.
The Flexible Choledochoscope is designed for use in adults.

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:	Apr./17/2023
Manufacturer:	Shanghai AnQing Medical Instrument Co., Ltd. 3 & 4 Floor, No.2 Building, 366 Huiqing Rd, East Zhangjiang High-Tech Park, 201201 Shanghai, China
Contact Person:	Shuwen Fan RA Manager Shanghai AnQing Medical Instrument Co., Ltd. Tel: +86-21-61117375 Fax: +86-21-61117374 ra_dept@anqing-sh.com

Identification of the Device:

Proprietary/Trade Name:	Flexible Choledochoscope
Model：	CS50H-20EU, CS50H-20US
Common name:	Choledochoscope And Accessories, Flexible/Rigid
Classification Name:	Endoscope and accessories
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FBN
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Identification of the Legally Marketed Predicate Device:

Trade Name:	CHF-V Choledocho Videoscope
Common name:	Choledochoscope And Accessories, Flexible/Rigid
Classification Name:	Endoscope and accessories
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FBN
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Submitter/510(k) Holder:	OLYMPUS MEDICAL SYSTEMS CORP.
Clearance:	K081456 (cleared November 6, 2008)

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

Device Description:
The Flexible Choledochoscope (Model: CS50H-20EU, CS50H-20US) is a sterile single-use endoscope which is used with the video processor (Model: EOS-H-01, FDA cleared #K211169) produced by AnQing for providing endoscopic imaging within the bile duct for the purpose of diagnosis and treatment.

The 2 proposed models are identical except the deflection versions, which is opposite from each other (EU version or US version).

The Flexible Choledochoscope is a single-use endoscope, which consists of Handle, Insertion Section, Distal Tip, and Endoscope Connector. The handle includes a deflection lever, a lever lock, an aspiration button, an aspiration connector, a push button for picture taking/video recording and a Luer port for insertion of accessory devices and irrigation to the working channel. The insertion section contains one working channel and wiring to transmit the image signals to the Video Processor. The distal bending section of the insertion section is controlled by the user via the deflection lever on the handle. The distal end of the insertion section contains a CMOS sensor for capturing image and transmitting it to the Video Processor, LEDs for illumination, and the distal opening of the working channel. The endoscope connector connects the endoscope handle to the video processor, which provides power and processes video signals from the endoscope.

Mechanism of action:
The light emitted by the LED cold light source at the distal tip of the disposable Flexible Choledochoscope 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 Video Processor via the VI circuit. The Video Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the attached monitor. The video processor also controls the brightness of the LEDs on the endoscope.

Flexible Choledochoscope 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:

AnQing Medical Flexible Choledochoscope has been designed to be used with the video processor, monitor, endotherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct.

The Flexible Choledochoscope is designed for use in adults.

Comparison with Predicate Device:
The Flexible Choledochoscope and its predicate device, the Olympus CHF TYPE V(K081456), have the same intended use, and similar physical characteristics, optical characteristics.

Substantial Equivalence:
The Flexible Choledochoscope employs the same fundamental scientific technology as its predicate device, as below table:

	Subject Device (CS50H-20EU, CS50H-20US)	Predicate Device, (CHF TYPE V) (K081456)	Comparison
Indications For Use			
Indications For Use:	AnQing Medical Flexible Choledochoscope has been designed to be used with the video processor, monitor, endotherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct. The Flexible Choledochoscope is designed for use in adults.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct.	Equivalent See Note1.
Physical Characteristics			
Type of Scope	Flexible	Flexible	Same
Outer diameter (mm)	Max. 5.0 mm	Max. 5.85 mm	Similar See Note2.
Inner diameter	Min. 2.0 mm	Min. 2.0 mm	Same

	Subject Device (CS50H-20EU, CS50H-20US)	Predicate Device, (CHF TYPE V) (K081456)	Comparison
(mm)			
Working length	380 mm	380mm	Same
Deflection	210°up, 180°down	160° up, 130° down	Similar See Note2.
Optical Characteristics			
Type of Image sensor	CMOS	Color CCD	Different See Note2.
Field of View	110°	120°	Similar See Note2.
Direction of View	0°	0°	Same
Depth of Field	5mm~100mm	3mm~50mm	Similar See Note2.
Light Source	Internal LEDs	External light source	Different See Note2.
Patient Contacting Materials			
General material type of main patient-contact part	Compliance with ISO10993-1	Compliance with ISO10993-1	Similar See Note2.
Duration and type of contact	"External communication medical device-Tissue" with a contact duration of "Limited (< 24 hours)"	"External communication medical device-Tissue" with a contact duration of "Limited (< 24 hours)"	Same
Sterilization Methods			
Number of Users	Single-Use	Reusable	Different See Note2
Sterilization	EO Sterilized, SAL 10^{-6}	Not provided sterile but intended for sterilization at the Medical Facility.	Different See Note2
Technological Characteristics			
Environment	Healthcare facility/hospital	Healthcare	Same

	Subject Device (CS50H-20EU, CS50H-20US)	Predicate Device, (CHF TYPE V) (K081456)	Comparison
of use		facility/hospital	
Energy source	Electricity	Electricity	Same
Note: 1. The indications for use statement for the subject Choledochoscope is very similar to that of the predicate device. A slightly different is wording description. The differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate. 2. The subject and predicate device have the same fundamental technology, type of scope, Working length, Direction of View, Inner diameter, contact duration and contact type, and environment of use. The subject Choledochoscope differs from the predicate in Outer diameter, Type of Image Sensor, Light source, Deflection, Field of View, Depth of Field, Sterilization method, Number of uses and patient-contacting materials. These differences do not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing and EO Sterilization validation.			

Summary of Testing:

Summary of Non-Clinical Tests:

Electrical Safety and Electromagnetic Compatibility Summary

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

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
- IEC 60601-2-18 Edition 3.0 2009-08
- IEC/TR 60601-4-2 Edition 1.0 2016-05

Bench Testing Summary

Photobiological safety

The LEDs in submitted Choledochoscope were tested according to the following FDA recognized standards:

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

Mechanical and Optical Performance

The Flexible Choledochoscope 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.

In addition, comparative testing related to image quality parameters was performed for submitted Flexible Choledochoscope and the predicate device to support substantial equivalence.

Biocompatibility Summary

The biocompatibility evaluation for the patient contacting components of the Flexible Choledochoscope was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted based contact category of "External communication medical device -Tissue" with a contact duration of "Limited (< 24 hours):

- Cytotoxicity: ISO 10993-5:2009
- Sensitization, Intracutaneous reactivity/irritation: ISO 10993-10:2010
- Material-mediated pyrogenicity: ISO 10993-11:2017
- Acute systemic toxicity: ISO 10993-11:2017

Sterilization and shelf life 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 Flexible Choledochoscope is determined based on stability study which includes ageing test according to ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier.

Package Validation

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F88/F88M-21, ASTM F1929-15.

Transport and shipping testing as per ASTM D4169-22.

Summary of 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 Flexible Choledochoscope is substantially equivalent to the predicate device.