March 6, 2024

Shenzhen HugeMed Medical Technical Development Co., Ltd
% Yang Jie
Consultant
Shenzhen Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue
Nanshan District
Shenzhen, Guangdong 518067
China

Re: K231497
Trade/Device Name: Choledochoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, FET
Dated: February 5, 2024
Received: February 5, 2024

Dear Yang Jie:

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)*
K231497

Device Name
Choledochoscope System

Indications for Use *(Describe)*
Choledochoscope System is intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct.
The image processor provides illumination for the choledochoscope, and is also used to receive the signal from the endoscope, convert it into an image and display it on the examination monitor.
The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/05/05

1. Submission sponsor

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3. Subject Device Information

Trade/Device Name	Choledochoscope System
Model	single-use Choledochoscope: CH-M50, CH-M52, CH-M40, CH-M32 image processor: HUV-01
Common Name	Choledochoscope System
Regulatory Class	Class II
Classification	21CFR 876.1500 / Choledochoscope And Accessories, Flexible/Rigid / FBN, FET
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K210579
Product name: WiScope® OM Endoscope System
Submitter: OTU Medical Inc.

5. Device Description

The Choledochoscope System consists of a single-use choledochoscope to provide illumination and intuitive images in endoscopic surgery of the pancreatic ductal system and

serves as a guide to diagnosis and management with accessories and an image processor for clinical image processing.

The single-use choledochoscope is a sterile single-use flexible choledochoscope and has the following 4 models:

Models	Description of similarities and difference
CHM32	The four models are the same except for the difference in the characteristics of the insertion tube, including diameter of the insertion tube, maximum insertion portion width and minimum insertion channel width.
CH-M40	
CH-M50	
CH-M52	

The image processor is a reusable monitor.

The single-use choledochoscope is comprised of a control body with articulation controls and accessory access ports, and a flexible insertion tube with an on-tip camera module and LED lighting source. The image processor processes the images from the choledochoscope and outputs video signals to a display.

6. Intended use & Indication for use

Choledochoscope System is intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct.

The image processor provides illumination for the choledochoscope, and is also used to receive the signal from the endoscope, convert it into an image and display it on the examination monitor.

The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

7. Comparison to the Predicate Device

Features	Subject Device	Predicate Device	Comparison
Trade name	Choledochoscope System	WiScope®OM Endoscope System	/
510(K) Submitter	Shenzhen HugeMed Medical Technical Development Co., Ltd.	OTU Medical Inc.	/
K number	K231497	K210579	/
Classification Regulation	21CRF 876.1500	21CRF 876.1500	Same

Features	Subject Device	Predicate Device	Comparison
Classification and Code	Class II, FBN, FET	Class II, FGB，FBN	Different
Common name	Choledochoscope and Accessories, Flexible/rigid	Choledochoscope and Accessories, Flexible/rigid	Same
Indication for use	Choledochoscope System is intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct. The image processor provides illumination for the choledochoscope, and is also used to receive the signal from the endoscope, convert it into an image and display it on the examination monitor. The instrument enables delivery and use of	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 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.	Different

Features	Subject Device	Predicate Device	Comparison
	accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.		
Item	Choledochoscope System - single-use Choledochoscope : CH-M50, CH-M52, CH-M40, CH-M32	WiScope OM Endoscope System - WiScope Single-Use Digital Flexible Ureteroscope. Choledochoscope	
Choledochoscope	Single-Use	Single-Use	Same
Digital video technology	CMOS	CMOS	Same
Illumination	LED	LED	Same
Field of view (degree)	120°±15%	100°	Different
Working length (mm)	605	670	Different
Outer Shaft Diameter	CH-M52: Φ5.2±10%mm CH-M50: Φ5.0±10%mm CH-M40: Φ4.4±10%mm CH-M32: Φ3.2±10% mm	2.8mm	Different
Working Channel Diameter	CH-M52: Φ≥2.10 mm CH-M50: Φ2.8±10%mm CH-M40: Φ≥1.1 mm CH-M32: Φ1.2±10%mm	1.2mm	Different
Up/Down	210° upward and	UP: 275°	Different

Features	Subject Device	Predicate Device	Comparison
Deflection	210° downward	DOWN: 275°	
Direction of view (degree)	0°±10°	0°	Same
Camera Head Configurable	No	Yes	Different
Sterilization	EO SAL: 10^{-6}	EO SAL: 10^{-6}	Same
Packaging	Choledochoscope is packaged in a tray which is sealed by sterile barrier.	Ureteroscope/Choledochoscope is packaged in a tray which is sealed by sterile barrier.	Same
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Same
Cytotoxicity	Comply with ISO 10993-5, No cytotoxicity effect	Comply with ISO 10993-5, No cytotoxicity effect	Same
Irritation	Comply with ISO 10993-10, not an irritant	Comply with ISO 10993-10, not an irritant	Same
Sensitization	Comply with ISO 10993-10, not a sensitizer.	Comply with ISO 10993-10, not a sensitizer.	Same
Acute systemic toxicity & Material-Mediated Pyrogenicity	Comply with ISO 10993-11, no acute systemic toxicity, no temperature rise	Comply with ISO 10993-11, no acute systemic toxicity, no temperature rise	Same
Item	Choledochoscope System **-Image Processor HUV-01**	WiScope OM Endoscope System -WiScope Image System	
Output Formats	USB/DVI/S-Video/CVBS	USB/AV/HDMI	Different
Brightness Control	Yes	Yes	Same
White Balance	Yes	Yes	Same
Image/Video Capture	Yes	No	Different

Features	Subject Device	Predicate Device	Comparison
Separate monitor	Yes	Yes	Same
Reusability	Reusable	Reusable	Same
Electrical Performance	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Same

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the single-use choledochoscope was evaluated 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.

Sterilization and shelf life testing

The Single-use choledochoscope is provided sterile and its shelf-life is 3 years.
Sterilization Process has been validated accordance with ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F1886/F1886M-16, ASTM F88/F88M-15, ASTM F 1929-15.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Choledochoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was 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." The software for this device was considered as a "moderate" level of concern.

Bench performance testing

The following bench tests were performed:

1. Optical performance testing according to ISO 8600 series.
2. Color performance (color reproduction), geometric distortion, optical performance (resolution, depth of field and image intensity uniformity), SNR and dynamic range, image frame frequency and system delay test compared with the predicate device.
3. Mechanical testing including Working Channel Flow Rate, bending and Insertion Portion Leak testing.

9. Clinical study

No clinical study is included in this submission

10. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.