January 21, 2025

Shenzhen HugeMed Medical Technical Development Co., Ltd.
Cathy Shi
Regulatory Engineer
401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17
Bulan Road,Xialilang Community, Nanwan Street, Longgang Dist
Shenzhen, Guangdong 518112
China

Re: K241444
Trade/Device Name: Biliary Pancreaticobiliary Scope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, KQM, NTN, FET
Dated: May 15, 2024
Received: December 20, 2024

Dear Cathy Shi:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241444

Device Name

Biliary Pancreaticobiliary Scope System

Indications for Use *(Describe)*

The Biliary Pancreaticobiliary Scope System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.
The Biliary Pancreaticobiliary Scope System comprises two components: the Single-use Biliary Pancreaticobiliary Scope and the Image Processor.
The Single-use Biliary Pancreaticobiliary Scope is intended to provide direct visualization, illumination and to guide accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.
The Image Processor is intended to receive, process, and output images from the Single-use Biliary Pancreaticobiliary Scope for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

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) #: K241444

510(k) Summary

Prepared on: 2025-01-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Applicant Address	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road Xialilang Community, Nanwan Street, Longgang District Shenzhen Guangdong 518112 China
Applicant Contact Telephone	+86 13534156592
Applicant Contact	Ms. Cathy Shi
Applicant Contact Email	cathy.shi@hugemed.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Biliary Pancreaticobiliary Scope System
Common Name	Endoscope and accessories
Classification Name	Choledochoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FBN, KQM, NTN , FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142922	SpyGlass DS Direct Visualization System	FBN

Device Description Summary

21 CFR 807.92(a)(4)

The Biliary Pancreaticobiliary Scope System comprises two components: the Single-use Biliary Pancreaticobiliary Scope (model:CL-A, CL-B), and the Image Processor (model: HUV-02).
The Single-use Biliary Pancreaticobiliary Scope is a flexible scope, introduced into the pancreatico-biliary system via a duodenoscope.
The Single-use Biliary Pancreaticobiliary Scope comprises a handle, an insertion tube, and a connection cable.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Biliary Pancreaticobiliary Scope System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.
The Biliary Pancreaticobiliary Scope System comprises two components: the Single-use Biliary Pancreaticobiliary Scope and the Image Processor.
The Single-use Biliary Pancreaticobiliary Scope is intended to provide direct visualization, illumination and to guide accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.
The Image Processor is intended to receive, process, and output images from the Single-use Biliary Pancreaticobiliary Scope for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject and predicate device are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The devices have the same sterilization method, energy source, principle of operation and similar design with same parameters such as FOV, DOV, max. outer diameter of insertion section, deflection angle, minimum instrument channel width, work length etc. They have similar technological characteristics as below. These differences will not raise new question on safety and effectiveness of the proposed device.

1. The proposed image processor has more types of signal output than the predicate device to give physicians more usage options. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Biocompatibility testing

Biocompatibility of the Single-use Biliary Pancreaticobiliary Scope 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. The following tests were performed, as recommended:

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- Acute systemic toxicity
- Pyrogen

Sterilization and shelf life testing

The Single-use Biliary Pancreaticobiliary Scope is provided sterile and its shelf-life is 2 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 F1980-21 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 Biliary Pancreaticobiliary Scope 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, "Content of Premarket Submissions for Device Software Functions".

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 water resistance, deflection, irrigation and working channel system leakage, articulation reliability, attachment to duodenoscope reliability, duodenoscope compatibility, irrigation pump compatibility, accessory compatibility.

Animal testing

Animal testing has been conducted referring to FDA Guidance-General Considerations for Animal Studies Intended to Evaluate Medical Devices.

Clinical testing

Not Applicable.

Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed Biliary Pancreaticobiliary Scope System is substantially equivalent to the predicate device.