



November 13, 2023

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

Re: K231118
Trade/Device Name: Cystoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: October 13, 2023
Received: October 13, 2023

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,


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

Indications for Use

510(k) Number (if known)

K231118

Device Name

Cystoscope System

Indications for Use (Describe)

The single-use cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The single-use cystoscope is intended to provide visualization via image processor and can be used with endoscopic accessories. The cystoscope system is intended for use in a hospital environment or medical office environment. The cystoscope system is designed for use for adult patients requiring cystoscopy.

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: 2023/10/13

1. Submission sponsor

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3. Subject Device Information

Trade/Device Name	Cystoscope System
Model	single-use Cystoscope: CY-M52, CY-M50, CY-M40, CY-M32 image processor: HUV-01
Common Name	Cystoscope System
Regulatory Class	Class II
Classification	21CFR 876.1500 / Endoscope and Accessories / FAJ
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K193095
Product name: Ambu aScope 4 Cysto
Submitter: Ambu Inc.

5. Device Description

The Cystoscope System consists of a single-use Cystoscope to provide illumination and intuitive images in endoscopic surgery of the lower urinary tract and serves as a guide to diagnosis and management with accessories and an image processor for clinical image

processing.

The single-use Cystoscope is a sterile single-use flexible Cystoscope. The image processor is a reusable monitor.

The single-use Cystoscope 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 Cystoscope and outputs video signals to a display.

6. Intended use & Indication for use

The single-use cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The single-use cystoscope is intended to provide visualization via image processor and can be used with endoscopic accessories. The cystoscope system is intended for use in a hospital environment or medical office environment. The cystoscope system is designed for use for adult patients requiring cystoscopy.

7. Comparison to the Predicate Device

Features	Subject Device	Predicate Device	Comparison
Trade name	Cystoscope System	Ambu® aScope™ 4 Cysto	/
510(K) Submitter	Shenzhen HugeMed Medical Technical Development Co., Ltd.	Ambu Inc.	/
K number	-	K193095	/
Classification Regulation	21CFR 876.1500	21CFR 876.1500	Same
Classification and Code	Class II, FAJ	Class II, FAJ	Same
Common name	Cystoscope and Accessories,, Flexible/rigid	Cystoscope and Accessories,, Flexible/rigid	Same
Cystoscope	Single-Use	Single-Use	Same
Indication for use	The single-use cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower	Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the	Same

Features	Subject Device	Predicate Device	Comparison
	urinary tract. The single-use cystoscope is intended to provide visualization via image processor and can be used with endoscopic accessories. The cystoscope system is intended for use in a hospital environment or medical office environment. The cystoscope system is designed for use for adult patients requiring cystoscopy.	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.	
Digital video technology	CMOS	CMOS	Same
Illumination	LED	LED	Same
Field of view (degree)	120°	120°	Same
Working length (mm)	350 mm±10%	390mm	Different
Outer Shaft Diameter	CY-M52: Φ5.0 CY-M50: Φ5.0 CY-M40: Φ4.2 CY-M32: Φ3.1	16.2Fr(5.4mm)	Different
Working Channel Diameter	CY-M52: Φ≥2.10 mm CY-M50: Φ2.8±10%mm CY-M40: Φ≥1.1 mm CY-M32: Φ1.2±10%mm	6.6Fr(2.2mm)	Different
Up/Down Deflection	210° upward and 210° downward	UP: 210° DOWN: 120°	Different
Sterilization	EO SAL: 10 ⁻⁶	EO SAL: 10 ⁻⁶	Same
Packaging	Cystoscope is packaged in a tray which is sealed by sterile barrier.	Cystoscope is packaged by paper-plastic bag.	Same
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Same

Features	Subject Device	Predicate Device	Comparison
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

8. Performance Data

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

Biocompatibility testing

Biocompatibility of the single-use Cystoscope 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 Cystoscope 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 Bronchoscope 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 the following:
 - Force/bending/tensile stress testing of the insertion portion
 - Force testing of the electrical cable to determine resistance to disconnection from the cystoscope handle and image system
 - Irrigation flow testing through the working channel
 - Functionality of Type T valve, including sealing
 - Functionality of the suction joint
 - Functionality of the image capture and video recording functions
 - Compatibility with endoscopic accessories without damage to the cystoscope

9. Clinical study

No clinical study is included in this submission

10. Conclusion

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