December 18, 2024

Hunan Vathin Medical Instrument Co. Ltd
Charlene Du
RA Manager
1/F, Bldg 12, Innovation and Entrepreneurship Service Center
No 9 Chuanqi West Road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
CHINA

Re: K242535
Trade/Device Name: Single-use Flexible Cystoscope (CY-E2E01, CY-E2E01R, CY-E2F01, CY-E2F01R, CY-E2G01, CY-E2G01R, CY-S2E01, CY-S2E01R); Digital Video Monitor (DVM-D1, DVM-D2)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: November 25, 2024
Received: November 25, 2024

Dear Charlene Du:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242535

Device Name

Single-use Flexible Cystoscope (CY-E2E01, CY-E2E01R, CY-E2F01, CY-E2F01R, CY-E2G01, CY-E2G01R, CY-S2E01, CY-S2E01R);
Digital Video Monitor (DVM-D1, DVM-D2)

Indications for Use *(Describe)*

The Single-Use Flexible Cystoscope is designed to be used with the Vathin Display Unit, endotherapy accessories and other auxiliary device for endoscopy and treatment of adult bladder.

The Digital Video Monitor is specially designed to be used with Vathin medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.

The devices are for use in professional Healthcare Facility 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.

510(k) Summary

I Submitter

Device submitter:	Hunan Vathin Medical Instrument Co., Ltd.
Address:	1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
Contact person:	Du Jing Title: Regulatory Affairs Manager Phone: +86-731-5558558 E-mail: charlene@vathin.com
Date of prepared:	December 18, 2024

II Device

Trade Name of Device:	Single-use Flexible Cystoscope Digital Video Monitor
Common name:	Endoscope and Accessories
Classification name:	Cystoscope and Accessories, Flexible/rigid
Regulation number:	21 CFR 876.1500
Regulatory Class:	Class II
Product Code:	FAJ
Review Panel:	Gastroenterology/Urology

III Predicate device and reference device

	Predicate device	Reference device
Trade name:	Ambu AScope 4 Cysto	Ambu aView™ 2 Advance
Regulation number:	21 CFR 876.1500	21 CFR 874.4680
Regulation name:	Endoscope and accessories	Bronchoscope (Flexible Or Rigid)
Regulatory class:	Class II	Class II
Product code:	FAJ	EOQ
Submitter:	Ambu A/S	Ambu A/S
510(k) number:	K193095	K223299

IV Device description

The device consists of a Single-use Flexible Cystoscope and a Digital Video Monitor for endoscopic image processing and displaying. They are used in conjunction with other accessories for the endoscopy and treatment of adult bladder.

V Indications for use

The Single-Use Flexible Cystoscope is designed to be used with the Vathin Display Unit, endotherapy accessories and other auxiliary device for endoscopy and treatment of adult bladder.

The Digital Video Monitor is specially designed to be used with compatible Vathin endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.

The device is for use in professional Healthcare Facility Environment.

VI Comparison of technological characteristics with the predicate devices

The device is similar to the predicate device in the following areas:

- Intended use (including intended use, intended user and patient population)
- Operation principle
- Design and performance specifications
- Digital video technology and illumination source
- It allows for irrigation
- It is single-use and delivered sterile

The device is different to the predicate device in the following areas:

- The field of view is slightly smaller than that of the predicate device
- The bending angle is larger than that of the predicate device
- There are 8 specifications while predicate device has 2 specification
- Working length is 400mm while working length of predicate device is 390mm

The differences between the device and predicate device do not alter suitability of the proposed device for its intended use.

Table 1 Substantial Comparison (Single-use Flexible Cystoscope)

Device feature	**Proposed Device**	**Predicate Device**
Trade Name	**Single-Use Flexible Cystoscope**	**Ambu AScope 4 Cysto (K193095)**
Classification Name	Cystoscope and Accessories, Flexible/rigid	Cystoscope and Accessories, Flexible/rigid
Product Code	FAJ	FAJ

Device feature	Proposed Device	Predicate Device
Trade Name	**Single-Use Flexible Cystoscope**	**Ambu AScope 4 Cysto (K193095)**
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Intended use	The Single-Use Flexible Cystoscope is designed to be used with the Vathin Display Unit, endotherapy accessories and other auxiliary device for endoscopy and treatment of adult bladder.	The aScope 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The aScope 4 Cysto is intended to provide visualisation via Ambu displaying units and can be used with endoscopic accessories. The aScope 4 Cysto is intended for use in a hospital environment or medical office environment. The aScope 4 Cysto is designed for use in adults.
The compatible Display Unit	Device Name： Digital Video Monitor Models:DVM-D1, DVM-D2	Ambu aView 2 Advance
Application field	The device is for use in a hospital or qualified medical institution.	The aScope 4 Cysto is intended for use in a hospital environment or medical office environment.
Intended user	The device is only to be used by skilled medical staff trained in clinical endoscopic techniques and procedures.	Before initial use of the aScope 4 Cysto, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions described in these instructions.
Patient population	Adults	Adults
Scope type	Flexible	Flexible
Field of view	110°	120°
Bending angle	Up: 210° Down: 210°	Up: 210° Down: ≥120°
Instrument Channel ID(mm)	CY-E2E01, CY-E2E01R, CY-S2E01, CY-S2E01R: 2 CY-E2F01, CY-E2F01R: 2.2 CY-E2G01, CY-E2G01R: 2.4	2.2

Device feature	Proposed Device	Predicate Device
Trade Name	**Single-Use Flexible Cystoscope**	**Ambu AScope 4 Cysto (K193095)**
Maximum outer diameter of insertion part (mm)	CY-E2E01, CY-E2E01R, CY-S2E01, CY-S2E01R: 5.25 CY-E2F01, CY-E2F01R: 5.45 CY-E2G01, CY-E2G01R: 5.65	6.0
Outer diameter of main hose (mm)	CY-E2E01, CY-E2E01R, CY-S2E01, CY-S2E01R: 4.9 CY-E2F01, CY-E2F01R: 5.1 CY-E2G01, CY-E2G01R 5.3	5.4
Distal end OD(mm)	CY-E2E01, CY-E2E01R, CY-S2E01, CY-S2E01R: 5.1 CY-E2F01, CY-E2F01R: 5.3 CY-E2G01, CY-E2G01R: 5.5	5.4
Working length (mm)	400	390
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibility	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization	No Cytotoxicity No Irritation to Skin No significant evidence of sensitization
Sterilization	EO	EO

Table 2 Substantial Comparison (Digital Video Monitor)

Device feature	Proposed Device	Reference Device
Trade Name	Digital Video Monitor	Ambu® aView™ 2 Advance (K223299)
Classification Name	Cystoscope and Accessories, Flexible/rigid	Bronchoscope (Flexible or Rigid) and Accessories
Product Code	FAJ	EOQ
Regulation	21 CFR 876.1500	21 CFR 874.4680

Device feature	Proposed Device	Reference Device
Number		
Models	Digital Video Monitor: DVM-D1, DVM-D2	Ambu® aView™ 2 Advance
Intended use	The Digital Video Monitor is specially designed to be used with Vathin medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.	The Ambu® aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.
Application field	The device is for use in a hospital or qualified medical institution.	For in-hospital use.
Intended user	For use by trained clinicians/physicians only.	For use by trained clinicians/physicians only.
Max. resolution	1920 * 1080	1920 * 1080
Display type	15.6" touch screen	12.8” colour TFT LCD
USB connection	A-type	Type A
Video output	HDMI, SDI	HDMI, 3G-SDI
Image/Video capture	Yes	Yes

VII Summary of Non-clinical performance tests:

Biocompatibility testing

Biocompatibility of the Single-Use Flexible Cystoscope was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity. All evaluation acceptance criteria were met.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2, IEC 60601-4-2 for EMC.

Sterilization validation

EO sterilization of the Single-use Flexible Cystoscope has been validated according to ISO 11135.

Shelf life and Packaging testing

Shelf Life and Sterile Barrier System of the Single-use Flexible Cystoscope have been validated. Packaging integrity testing and product performance testing were carried out following the accelerated aging of the final devices per ASTM F1980-21 and simulated transportation distribution according to ASTM D4169-22.

Software Verification and Validation

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".

Cybersecurity testing

Cybersecurity testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Bench performance testing

Bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to the predicate device. The following performance testing was conducted.

Bench testing - Mechanical Performance

The mechanical performance testing was conducted in accordance with applicable parts of ISO 8600-1, ISO 8600-4.

Bench testing – Optical Performance

- Field of view
- Direction of view
- Depth of field
- Geometric distortion
- Image intensity uniformity
- Color performance
- Signal-To-Noise Ratio
- Dynamic Range

Bench testing – Photobiological Safety

The subject device was tested according to FDA recognized standards IEC 62471:2006.

VIII Conclusion

The device is substantially equivalent to predicate device. The non-clinical performance testing

demonstrates that the device is as safe, as effective and performs as well as the legally marketed predicate device.