November 17, 2022

Hunan Vathin Medical Instrument Co., Ltd.
Du Jing
RA Manager, RA Department
1/F, Building 12, Innovation and Entrepreneurship Service
Ctr, No. 9 Chuanqi West Road Jiuhua Economic Dev. Zone
Xiangtan, Hunan 411100
CHINA

Re: K221580
Trade/Device Name: Single-Use Flexible Cystoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: October 19, 2022
Received: October 19, 2022

Dear Du Jing:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 J. Antonino -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221580

Device Name
Single-use Flexible Cystoscope

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.

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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Section 5 510(k) summary

II 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: RA Manager Phone: +86-731-55558558 E-mail: charlene@vathin.com

II Device

Trade Name of Device: Single-Use Flexible Cystoscope

Common name: Cystoscope and Accessories, Flexible/rigid

Classification: Class II, 21 CFR 876.1500

Product Code: FAJ

Review Panel: Gastroenterology/Urology

III Predicate Device

Trade name:	Ambu AScope 4 Cysto
Regulation number:	21 CFR 876.1500
Regulation name:	Cystoscope and Accessories, Flexible/rigid
Regulatory class:	Class II
Product code:	FAJ
Submitter:	Ambu A/S
510(k) number:	K193095

IV Device description

The Single-use Flexible Cystoscope can be connected to the compatible Vathin Display Units and 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.

VI Comparison of technological characteristics with the predicate devices

The Single-Use Flexible Cystoscope is similar to the predicate device in the following areas:

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

The Single-Use Flexible Cystoscope is different to the predicate device in the following areas:

- The bending angle is larger than the predicate
- There are 10 specifications while predicate device has 1 specification
- Working length is 450mm while working length of predicate device is 390mm

The differences between the Single-Use Flexible Cystoscope and predicate device do not alter suitability of the proposed device for its intended use.

VII Summary of Non-clinical 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 Single-Use Flexible Cystoscope. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Performance Testing

The following performance testing was conducted on the Single-Use Flexible Cystoscope:

- Appearance
- Working length
- Work channel ID
- Head OD

- Outer diameter of main hose
- Maximum outer diameter of the insertion part
- Bending angle
- Product weight
- Rotating sleeve
- Handle-based photographing function
- Cable length
- Image display
- Waterproofness
- Direction of view
- Lens fogging
- Image quality
- LED illuminance test
- LED color temperature test
- Air tightness test
- Suction ability
- Water delivery ability
- LED temperature test
- Handle-based camera button reliability test
- field of view test
- resolution test
- observation depth of field test
- geometric distortion test
- SNR test
- dynamic tolerance test
- brightness uniformity test
- color reduction test

VIII Conclusion

The Single-Use Flexible Cystoscope is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is safe and effective.