June 14, 2023

Hunan Vathin Medical Instrument Co., Ltd.
Du Jing
RA Manager
1/F, Building 12, Innovation and Entrepreneurship Service
Center No 9 Chuanqi west road, Jiuhua Economic Development
Xiangtan, Hunan 411100
China

Re: K230536
Trade/Device Name: Single-use Flexible Rhinolaryngoscope; Digital Video Monitor
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 15, 2023
Received: May 15, 2023

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K230536

Device Name
Vathin® Video Rhinolaryngoscope System

Indications for Use *(Describe)*
The Single-use Flexible Rhinolaryngoscope is designed to be used with the Digital Video Monitor, for examination of nasal cavity and upper respiratory tract. For Rhinolaryngoscope models that include a working channel and permit the use of a compatible 3rd party accessory, treatment is also possible.
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 Vathin® Video Rhinolaryngoscope System is for use in a hospital 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# K230536 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<br>Title: Regulatory Affairs Manager<br>Phone: 4000789990<br>E-mail: charlene@vathin.com |

## II Device

| | |
|---|---|
| Trade Name of Device: | Vathin® Video Rhinolaryngoscope System |
| Model: | Single-Use Flexible Rhinolaryngoscope<br>RL-S1800, RL-S1801, RL-E1800, RL-E1801, RL-S1E00, RL-S1E01, RL-E1E00, RL-E1E01<br><br>Digital Video Monitor<br>DVM-A1, DVM-A2, DVM-B1, DVM-B2 |
| Regulation number: | 21 CFR 874.4760 |
| Regulation name: | Nasopharyngoscope (flexible or rigid) and accessories |
| Regulation Class: | II |
| Product Code: | EOB |
| Review Panel: | Ear Nose & Throat |

## III Predicate Device and reference device

| - | **Predicate Device** | **Reference Device** |
|---|---|---|
| Trade name: | Ambu AScope 4 RhinoLaryngo Intervention | Ambu® aView Monitor |
| Regulation number: | 21 CFR 874.4760 | 21 CFR 874.4680 |
| Regulation name: | Nasopharyngoscope, Flexible or rigid | Bronchoscope (Flexible or Rigid) and Accessories |
| Regulatory class: | Class II | Class II |
| Product code: | EOB | EOQ |
| Submitter: | Ambu A/S | Ambu A/S |
| 510(k) number: | K190972 | K173727 |

## IV Device description

The Vathin® Video Rhinolaryngoscope System consists of Single-use flexible Rhinolaryngoscope (eight models shown in below) and Digital Video Monitor (model: DVM-A1, DVM-A2, DVM-B1, DVM-B2) for clinical image processing and display.

The Single-use Flexible Rhinolaryngoscope is designed for use with Vathin Display Units, for examination of nasal cavity and upper respiratory tract. For Rhinolaryngoscope models that include a working channel and permit the use of a compatible 3rd party accessory, treatment is also possible.
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.

There are eight subject nasopharyngoscope models: RL-S1800, RL-S1801, RL-E1800, RL-E1801, RL-S1E00, RL-S1E01, RL-E1E00, RL-E1E01. The main differences between product models are in the working channel inner diameter (whether channel is present or not), outer diameter, and rotate function.

Single-use flexible Rhinolaryngoscope is a sterile single used flexible Rhinolaryngoscope. Digital Video Monitor is a reusable monitor.
The light emitted by the LED cold light source of the Single-use flexible Rhinolaryngoscope lens is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is imaged on the CMOS (complementary metal oxide semiconductor). The CMOS acquisition image is controlled by the CMOS drive circuit, and the standard color video signal is output to the Digital Video Monitor via the encoding circuit. The Digital Video Monitor adjusts the brightness of the light source or corrects the image according to the video signal output from the CMOS, and outputs the corrected standard color video signal.
Single-use flexible Rhinolaryngoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

The differences between the Single-use flexible Rhinolaryngoscope models are as follow:

- Have or haven’t working channel
- Working channel inner diameter
- Insertion tube outer diameter
- The length of insertion tube

**V Indications for use**

The Single-use Flexible Rhinolaryngoscope is designed to be used with the Digital Video Monitor, for examination of nasal cavity and upper respiratory tract. For Rhinolaryngoscope models that include a working channel and permit the use of a compatible 3rd party

accessory, treatment is also possible.
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 Vathin® Video Rhinolaryngoscope System is for use in a hospital environment.

**VI Comparison of technological characteristics with the predicate device and reference devices**

The Single-Use Flexible Rhinolaryngoscope has the same intended use and principal operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. Any differences in various attributes as listed below between the Single-Use Flexible Rhinolaryngoscope and predicate device do not alter suitability of the proposed device for its intended use nor impact substantial equivalence with the predicate.
The Single-Use Flexible Rhinolaryngoscope are identical to the ones cleared in K221581, and so any differences in bending angle, etc. were previously compared.

| Device feature | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Trade Name | **Single-Use Flexible Rhinolaryngoscope** | **Ambu AScope 4 RhinoLaryngo Intervention (K190972)** | / |
| Classification Name | Nasopharyngoscope, Flexible or rigid | Nasopharyngoscope, Flexible or rigid | Same |
| Product Code | EOB | EOB | Same |
| Regulation Number | 21 CFR 874.4760 | 21 CFR 874.4760 | Same |
| Intended use | The Single-use Flexible Rhinolaryngoscope is designed for use with Vathin Display Units, for examination of nasal cavity and upper respiratory tract. For Rhinolaryngoscope models that include a working channel and permit the use of a compatible 3rd party accessory, treatment is also possible. | The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via a monitor. | Same |
| Application field | The device is for use in a hospital or qualified medical institution. | The endoscope is intended for use in a hospital environment. | Same |

| Device feature | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Trade Name | **Single-Use Flexible Rhinolaryngoscope** | **Ambu AScope 4 RhinoLaryngo Intervention (K190972)** | / |
| 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 RhinoLaryngo Intervention 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 mentioned in these instructions. | Same |
| Patient population | Adults | Adults | Same |
| Scope type | Flexible | Flexible | Same |
| Field of view (degree) | 110° | 85° | *1 |
| Direction of view (degree) | 0° | 0° | *1 |
| Bending angle (degree) | Up: 210°<br>Down: 210° | Up: 130°<br>Down: 130° | *2 |
| Maximum insertion portion width(mm) | RL-S1800、RL-S1801、RL-E1800、RL-E1801：3.2<br><br>RL-S1E00、RL-S1E01、RL-E1E00、RL-E1E01：5.0 | 5.5 | *3 |
| Minimum insertion channel width(mm) | RL-S1800、RL-S1801、RL-E1800、RL-E1801：0<br><br>RL-S1E00、RL-S1E01、RL-E1E00、RL-E1E01：2.2 | 2.0 | *4 |
| Working length (mm) | 300 | 350 | *5 |
| Illumination source | LED | LED | Same |
| Single-use | Yes | Yes | Same |
| Biocompatibility | No Cytotoxicity | No Cytotoxicity | Same |
| | No Irritation to Skin | No Irritation to Skin | Same |
| | No significant evidence of sensitization | No significant evidence of sensitization | Same |

| Device feature | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Trade Name | **Single-Use Flexible Rhinolaryngoscope** | **Ambu AScope 4 RhinoLaryngo Intervention (K190972)** | **/** |
| | No pyrogen | No pyrogen | Same |
| Sterilization | EO | EO | Same |

Compared with K221581, only the monitors are being updated in the present 510(k). Because the monitor is required to be connected during the use of the Ambu AScope 4 RhinoLaryngo Intervention, the Ambu aView used with Ambu AScope 4 is selected as the reference device for the Digital Video Monitor.

| Device feature | Proposed Device | Reference Device | Remark |
|---|---|---|---|
| Trade Name | **Digital Video Monitor** | Ambu® aView Monitor (K173727) | **/** |
| Classification Name | Nasopharyngoscope, Flexible or rigid | Bronchoscope (Flexible or Rigid) and Accessories | *6 |
| Product Code | EOB | EOQ | *6 |
| Regulation Number | 21 CFR 874.4760 | 21 CFR 874.4680 | *6 |
| Models | Digital Video Monitor:<br>DVM-A1, DVM-A2,<br>DVM-B1, DVM-B2 | Ambu® aView Monitor | / |
| Intended use | 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 aViewTM monitor is a non-sterile, reusable digital monitor, intended to display live imaging data from Ambu visualisation devices. | / |
| Application field | The device is for use in a hospital or qualified medical institution. | For in-hospital use. | Same |
| Intended user | For use by trained clinicians/physicians only. | For use by trained clinicians/physicians only. | Same |
| Max. resolution | 1280 x 800 | 800 * 480 | / |
| Display type | 12.1" touch screen | 8.5” colour TFT LCD | / |
| USB connection | A-type | Type A | Same |
| Video output | HDMI/USB 2.0 | RCA connection (use adapter | / |

| Device feature | Proposed Device | Reference Device | Remark |
|---|---|---|---|
| | | cable included) | |
| Image/Video capture | Yes | Yes | Same |

**Note: Explain the conclusion.**

***1: Field of view:** Because the Field of view is larger, it means more content can be seen, which is beneficial for the clinical use of the product.

***2: Bending angle:** Because the Bending angle is larger, it means more flexibility in clinical use.

***3: Maximum insertion portion width**：In a comprehensive comparison, the Proposed Device has a smaller outer diameter than the Predicate Device, which means that it can enter the patient's body more easily during clinical use.

***4: Minimum insertion channel width**：In a comprehensive comparison, the Proposed Device has a larger inner diameter than the Predicate Device, which means that it is more convenient for doctors to operate in clinical use.

***5: Working length**：The length of 300mm meets the needs of clinical use, and it is considered that the Working length is substantially equivalent.

***6: Classification name/product code/Regulation Number**: The predicate device itself does not contain a monitor, it is intended to be used with the Aview Monitor which is included in the 510(k) number K173727.

**VII Summary of Non-clinical tests:**

**Biocompatibility testing**

Biocompatibility of the Single-Use Flexible Rhinolaryngoscope 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 Vathin® Video Rhinolaryngoscope System. 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 Vathin® Video Rhinolaryngoscope System.

**Appearance, dimensions and weight**

- Working length

- Bending angle
- Work channel ID
- Insert tube outside diameter
- Maximum outer diameter of insertion section
- Package reliability
- coaxiality deviation
- direction of view
- LED temperature test
- Product length
- Product weight
- Product appearance

**Functional performance**

- Attractive features
- Rotating sleeve function test
- Handle shape
- Wire length
- Hot-swap function
- Image display
- Edge uniformity
- Illuminated mirror light effect
- Field of view
- Observe the depth of field
- Field of view central angle resolution
- Field of view quality
- Colour rendering index
- Related colour temperatures
- Radiation flux ratio of red, green and blue light
- Infrared cut-off performance
- Brightness response characteristics
- Signal-to-noise ratio
- Spatial frequency response
- Still Image Tolerance
- Water delivery
- Volume of attraction

**VIII Conclusion**

The Vathin® Video Rhinolaryngoscope System is substantially equivalent to its proposed devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed predicate device cleared under K190972.