March 21, 2023

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

Re: K221581
Trade/Device Name: Single-Use Flexible Rhinolaryngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB

Dear Du Jing:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 18, 2022. Specifically, FDA is updating this SE Letter to reflect the enclosed Indications for Use Statement page where the "Prescription Use" box is checked, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D., Team Assistant Director, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (301) 796-6481, shu-chen.peng@fda.hhs.gov.

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

November 18, 2022

Hunan Vathin Medical Instrument Co., Ltd.
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Regulatory Class: Class II
Product Code: EOB
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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
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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)*
K221581

Device Name

Single-use Flexible Rhinolaryngoscope

Indications for Use *(Describe)*

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.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: RA Manager Phone: +86-18915069265 E-mail: charlene@vathin.com

II Device

Trade Name of Device: Single-Use Flexible Rhinolaryngoscope

Common name: Nasopharyngoscope, Flexible or rigid

Classification: Class II, 21 CFR 874.4760

Product Code: EOB

Review Panel: Ear Nose & Throat

III Predicate Device

Trade name:	Ambu AScope 4 RhinoLaryngo Intervention
Regulation number:	21 CFR 874.4760
Regulation name:	Nasopharyngoscope, Flexible or rigid
Regulatory class:	Class II
Product code:	EOB
Submitter:	Ambu A/S
510(k) number:	K190972

IV Device description

The Single-use Flexible Rhinolaryngoscope can be connected to the compatible Vathin Display Units and other accessories for examination and treatment of nasal cavity and upper respiratory tract.

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.

V Indications for 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.

VI Comparison of technological characteristics with the predicate 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.

Device feature	**Proposed Device**	**Predicate Device**
Trade Name	**Single-Use Flexible Rhinolaryngoscope**	**Ambu AScope 4 RhinoLaryngo Intervention (K190972)**
Classification Name	Nasopharyngoscope, Flexible or rigid	Nasopharyngoscope, Flexible or rigid
Product Code	EOB	EOB
Regulation Number	21 CFR 874.4760	21 CFR 874.4760
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.
Application field	The device is for use in a hospital or qualified medical institution.	The endoscope is intended for use in a hospital 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 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.
Patient population	Adults	Adults

Device feature	Proposed Device	Predicate Device
Trade Name	**Single-Use Flexible Rhinolaryngoscope**	**Ambu AScope 4 RhinoLaryngo Intervention (K190972)**
Scope type	Flexible	Flexible
Field of view (degree)	110°	85°
Direction of view (degree)	0°	0°
Bending angle (degree)	Up: 210° Down: 210°	Up: 130° Down: 130°
Maximum insertion portion width(mm)	RL-S1800、RL-S1801、RL-E1800、RL-E1801：3.2 RL-S1E00、RL-S1E01、RL-E1E00、RL-E1E01：5.0	5.5
Minimum insertion channel width(mm)	RL-S1800、RL-S1801、RL-E1800、RL-E1801：0 RL-S1E00、RL-S1E01、RL-E1E00、RL-E1E01：2.2	2.0
Working length (mm)	300	350
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibility	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No pyrogen	No pyrogen
Sterilization	EO	EO

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 Single-Use Flexible Rhinolaryngoscope. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Performance testing

Performance testing was conducted on the Single-Use Flexible Rhinolaryngoscope.

Compatible display units

Trade Name	Model	510(k) number:
Digital video monitor	DVM-A1、DVM-A2	K213635
Digital video processor	DVP-A1	K191828
SPiN VisionTM Video Processor	SYS-5100	K202346

VIII Conclusion

The Single-Use Flexible Rhinolaryngoscope is substantially equivalent to its predicate 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.