April 26, 2024

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: K232435
Trade/Device Name: Rhinolaryngoscope system
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 27, 2024
Received: March 27, 2024

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,

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)*
K232435

Device Name
Rhinolaryngoscope System

Indications for Use *(Describe)*
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 an Image Processor. The endoscope is intended for use in a hospital environment. It is designed for use in adults.

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

The assigned 510(k) number is K232435.

Prepared Date: 2024/04/25

1. Submission sponsor

Name: Shenzhen HugeMed Medical Technical Development Co., Ltd.
Address: 415, 416-1,516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street, Longgang District, Shenzhen, Guangdong, 518115, China
Contact person: Cathy
Title: Regulatory engineer
E-mail: cathy.shi@hugemed.cn
Tel: +86-755-22275833

2. Submission correspondent

Name: Shenzhen Chonconn Medical Device Consulting Co., Ltd.
Address: Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P.R. China
Contact person: Yang Jie
E-mail: yangjie@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Rhinolaryngoscope System
Model	Single-use Rhinolaryngoscope: RH-M58, RH-M52, RH-M50, RH-M40, RH-M32, RH-M22 Image Processor: VLM-02
Common Name	Rhinolaryngoscope System
Regulatory Class	Class II
Classification	21CFR 874.4760 / Nasopharyngoscope (flexible or rigid) and accessories / EOB
Submission type	Traditional 510(K)

4. Predicate Device

1) Predicate device
   510(k) number: K191080
   Product name: Ambu aScope 4 RhinoLaryngo Slim
   Submitter: Ambu Inc.
2) Reference device
   510(k) number: K190972
   Product name: Ambu AScope 4 RhinoLaryngo Intervention

Submitter: Ambu A/S

3) Reference device
510(k) number: K221581
Product name: Single-Use Flexible Rhinolaryngoscope
Submitter: Hunan Vathin Medical Instrument Co., Ltd.

5. Device Description

The Rhinolaryngoscope System consists of Single-Use Rhinolaryngoscope (six models shown in below) to be introduced within the nasal lumens and upper airway anatomy and Image Processor (model: VLM-02) for clinical image processing. The Image Processor provides power and processes the images for medical electronic endoscope.

System name	Component name	Model
Rhinolaryngoscope System	Single-Use Rhinolaryngoscope	RH-M58, RH-M52, RH-M50, RH-M40, RH-M32, RH-M22
	Image Processor	VLM-02

The Single-Use Rhinolaryngoscope is a sterile single used flexible Rhinolaryngoscope. The Image Processor is a reusable monitor.

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

- Have or haven't working channel
- Working channel inner diameter
- Insertion tube outer diameter

6. Intended use & Indication for use

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 an Image Processor.

The endoscope is intended for use in a hospital environment. It is designed for use in adults.

7. Comparison to the Predicate Device

The Rhinolaryngoscope System consists of Single-Use Rhinolaryngoscope (six models shown in below) and Image Processor (model: VLM-02). However, the Image Processor (model: VLM-02) has been cleared by K222910. The following lists the comparison with the predicate device for the Single-Use Rhinolaryngoscope.

Features	Subject Device	Predicate Device	Comparison
K number	K232435	K191080	/
Manufacturer	Shenzhen HugeMed Medical Technical	Ambu Inc.	/

Features	Subject Device	Predicate Device	Comparison
	Development Co., Ltd.		
Model	Single-use Rhinolaryngoscope: RH-M58, RH-M52, RH-M50, RH-M40, RH-M32, RH-M22	Ambu aScope 4 RhinoLaryngo Slim	/
Product code & Classification	21 CFR 874.4760, EOB Class II	21 CFR 874.4760, EOB Class II	Same
Intended use	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 an Image Processor. The endoscope is intended for use in a hospital environment. It is designed for use in adults.	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 Ambu displaying unit. The endoscope is intended for use in a hospital environment. It is designed for use in adults.	Same
Scope type	Flexible	Flexible	Same
Field of view (degree)	120°	85°	Similar Although the field of view is slightly different from the predicate device, the area

Features	Subject Device	Predicate Device	Comparison
			within the view can be adjusted by the advance or retreat of the endoscope. Therefore, the difference in FOV does not affect the safety and effectiveness of the subject device.
Direction of view (degree)	0°	0°	Same
Depth of Field	3-50mm	6-50mm	Similar The subject device has a wider range of depth of view than the predicate device to give physicians more options for diagnosis and treatment based on the patient's condition. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.
Bending angle (degree)	210° (up and down)	130° (up and down)	Different, but the K221581 reference device has the same 210° (up and down) Bending angle. Because the Bending angle is larger, it means more flexibility in clinical use. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.
Maximum insertion portion width(mm)	RH-M22: 2.2±10%mm RH-M32: 3.2±10%mm RH-M40: 4.4±10%mm	3.5 mm	Similar, and the K190972 reference device also has a similar 5.5 mm Maximum insertion portion width. The difference in Maximum insertion portion width for

Features	Subject Device	Predicate Device	Comparison
	RH-M50: 5.0±10%mm RH-M52: 5.2±10%mm RH-M58: 5.8±10%mm		the subject device does not alter or change the indications for use or result in a new intended use.
Minimum insertion channel width(mm)	RH-M22: / RH-M32: 1.2±10% mm RH-M40: Φ≥1.1 mm RH-M50: 2.8±10% mm RH-M52: Φ≥2.1 mm RH-M58: Φ≥2.50 mm	3.0mm	Similar The difference in Minimum insertion channel width for the subject device does not alter or change the indications for use or result in a new intended use.
Working length (mm)	350 mm	300 mm	Similar, and the K190972 reference device has the same 350 mm Working length. The length of 300mm meets the needs of clinical use. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.
Illumination Source	LED	LED	Same
LED Light source	At distal tip	At distal tip	Same
Single-use	Yes	Yes	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18	Same
Bench test	ISO 8600-1 ISO 8600-3 ISO 8600-4	ISO 8600-1 ISO 8600-3 ISO 8600-4	Same
Sterilization	EO Sterilization	EO Sterilization	Same

8. Performance Data

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

Biocompatibility testing

Biocompatibility of the Single-Use Rhinolaryngoscope 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. The following tests were performed, as recommended:

- Cytotoxicity
- Sensitization
- Oral Mucosa Irritation

The Single-Use Rhinolaryngoscope is considered surface – mucosal membrane contacting for a duration of less than 24 hours.

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Single-use Rhinolaryngoscope is validated.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Rhinolaryngoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

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 bending testing.
4. Photobiological safety test verified compliance to IEC 62471:2006
5. Thermal safety performance test verified compliance to Protection against excessive temperature and other safety hazards of IEC 60601-2-18:2009

9. Clinical study

No clinical study is included in this submission

10. Conclusion

Substantial equivalence comparisons, performance testing and compliance with voluntary

standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.