July 12, 2019

Ambu A/S
% Sanjay Parikh
Director, QA/RA
Ambu Inc.
6230 Old Dobbin Lane, Suite 250
Columbia, Maryland 21045

Re: K190972
Trade/Device Name: Ambu aScope 4 RhinoLaryngo Intervention
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: April 12, 2019
Received: April 15, 2019

Dear Sanjay Parikh:

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,

for Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190972

Device Name
Ambu aScope 4 RhinoLaryngo Intervention

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 a monitor.

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.

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

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510(k) Summary

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the content and format of the 510(k) summery has been prepared in accordance with 21 CFR 807.92.

Submitter	Ambu A/S Baltorpbakken 13 DK-2750 Ballerup Denmark Tel.: +45 7225 2000 Fax.: +45 7225 2050
Contact Person	Name: Gurpreet Kaur Rehal Job Title: Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup Telephone number: +45 7225 2116 Fax number: +45 7225 2050
Date Summary Prepared	April 12, 2019
Device Trade Name	Ambu® aScope™ 4 RhinoLaryngo Intervention
Device Common Name	Rhino-Laryngoscope
Device Classification	Nasopharyngoscopes (Flexible or Rigid) Product Codes: EOB 21 CFR 874.4760 Class II
Legally Marketed devices to which the device is substantially equivalent	<u>Predicate Device:</u> Olympus XENF-TP (K013591), Olympus Medical Systems Corporation <u>Reference Device:</u> Ambu® aScope™ 4 Broncho Regular (K173727), Ambu A/S

Description of the Device

The Ambu® aScope™ 4 RhinoLaryngo Intervention is a sterile single use flexible endoscope for examination of the nasal lumens and upper airway anatomy.

Ambu® aScope™ 4 RhinoLaryngo Intervention 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
- Working Channel
- Sterilized by Ethylene Oxide
- For single use

Indications 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 a monitor.

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

Summary of the technological characteristics in comparison to the predicate devices

Ambu® aScope™ 4 RhinoLaryngo Intervention is similar to the predicate device and reference device in the following areas:

- They are all flexible endoscopes with a maneuverable tip.
- They all have a handle with a control lever giving the operator ability to steer the tip of the scope up and down.
- They all provide illumination from the distal tip.
- They all have a working channel for insertion of endoscopic accessories.
- They all have the same “field of view” and “direction of view”
- They all have insertion cord diameters within the same range.
- They are all portable endoscopes.

	Subject (K190972)	Predicate (K013591)
Device Name	Ambu® aScope™ 4 RhinoLaryngo Intervention	Olympus XENF-TP
Type of product	Rhino-laryngo videoscope	Rhino-laryngo fiberscope
Design Concept	Portable design	Portable design
Separate Monitor required	Yes	Yes.
Connection to other devices	Monitor	Monitor
Delivered sterile	Yes	No, shall be cleaned or sterilized before use by user/hospital
Disposable after use	Yes	No
Field of view	85°	85°
Direction of View	0° (forward viewing)	0° (forward viewing)
Depth of field	6-50 mm	3-50 mm
Illumination method	LED	LED or halogen
Bending section	130° up 130° down	130° up 130° down
Maximum diameter of insertion portion	5.5 mm	5.0 mm
Working Channel (Inner diameter)	2.2 mm	2.2 mm
Working length	350 mm	365 mm

Performance Data –Bench

The following data have been submitted in the premarket notification:

Declaration of conformity to the following applicable recognized consensus standards:

- ISO 8600-1, ISO 8600-3 and ISO 8600-4 Optics and optical instruments – Medical endoscopes and certain accessories.

Result: All tests were passed.

Performance test reports to document the following properties:

- Bending Endurance and Angle
- Image Sharpness and Resolution
- Length of Insertion Cord
- Suction Capability

Result: All tests were passed.

	Performance test report to document shelf life. Tests were performed on finished, sterilized and aged products: • Performance test • Sterile Packaging Integrity Result: All tests were passed. Biocompatibility tests reports to document compliance with the requirements of ISO 10993-1: • Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous reactivity test (ISO 10993-10) Result: All tests were passed. Test reports that verify the Electromagnetic Compatibility and Electrical Safety: • Electromagnetic Compatibility in compliance with IEC 60601-1-2. • Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18. Result: All tests were passed.
Performance Data – Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate device it has been concluded that the functionality and intended use of Ambu® aScope™ 4 RhinoLaryngo Intervention is substantially equivalent to the predicate device. It is concluded that Ambu® aScope™ 4 RhinoLaryngo Intervention is as safe and as effective and perform as well as the predicate device.