May 22, 2019

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

Re: K191080
Trade/Device Name: Ambu aScope 4 RhinoLaryngo Slim
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: April 23, 2019
Received: April 24, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Michael Ryan
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)*
K191080

Device Name
Ambu aScope 4 RhinoLaryngo Slim

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 Special 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

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Date Summary Prepared

April 19, 2019

Device Trade Name

Ambu® aScope™ 4 RhinoLaryngo Slim

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

	Manufacturer	Trade Name	510k number
Predicate C:	Ambu A/S	Ambu® aScope™ RLS Slim	K181286
Reference: A:	Olympus Medical Systems Corporation	Olympus ENF-GP	K011869
Reference B:	Ambu A/S	Ambu® aScope™ 4 Broncho Slim	K173727

Description of the Device

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

Ambu® aScope™ 4 RhinoLaryngo Slim 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

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

The differences between the Ambu® aScope™ RhinoLaryngo endoscope sizes are as follows:

Specification	**Ambu® aScope™ RLS Slim**	**Ambu® aScope™ 4 RhinoLaryngo Slim**
Distal end diameter	4.2 mm (0.16”)	3.5 mm (0.14”)
Insertion cord diameter	3.8 mm (0.15”)	3.0 mm (0.12”)
Working length	600 mm (23.6”)	300 mm (11.8”)
Bending section	180° up, 180° down	130° up, 130° down
Max diameter of insertion portion	4.3 mm (0.17”)	3.5 mm (0.14”)

Ambu® aScope™ 4 RhinoLaryngo Slim is similar to the predicate device C and reference A and B devices 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 the same “field of view” and “direction of view”
- They all have insertion cord diameters within the same range.

The Ambu® aScope™ 4 RhinoLaryngo Slim diameter is similar to the predicate and reference device:

  - Predicate C has a larger diameter.
  - Reference A has the same working length. Predicate C and reference B have a longer working length

- Predicate C and Reference A have same intended use.
- Predicate C and reference B are single-use device, which are delivered sterile.

- They are all portable endoscopes.

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety and effectiveness of the applicant device. Overall, the line extension scope is narrower in diameter and shorter in length than the predicate device.

Furthermore, the following non-dimensional changes are made:

- The color of the control lever and tube connection has been changed from gray to purple, to indicate the product variant. The control lever and tube connector are components on the handle and do not have direct or indirect contact with the patient and do not raise new questions of safety and effectiveness.
- The type of Tyvek primary packaging material has been changed to Tyvek 2FS with EP 1250 film. Packaging integrity testing and sterilization validation report have been updated and do not raise new questions of safety and effectiveness.
- Adhesive used for water tightness of the camera is changed. Tests that documents compliance with design requirements are performed, including verification using ISO10993 tests for cytotoxicity, irritation and sensitization, and do not raise new questions of safety and effectiveness.

Performance Data –Bench

Ambu® aScope™ 4 RhinoLaryngo Slim has been successfully tested for its functions, performance and safety as per FDA recognized consensus standards.

The following bench data are described for the product line extension in the premarket notification:

Declaration of Conformity with the following product specific standards

- ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 594-1

Result: All tests were passed.

Performance test has been conducted to document the following properties of Ambu® aScope™ 4 RhinoLaryngo Slim:

- Length and diameters of insertion cord
- Bending angle, endurance and radius
- Image Sharpness

Result: All tests were passed.

Performance test has been conducted to document the shelf life and sterile barrier of Ambu® aScope™ 4 RhinoLaryngo Slim, where the aging and sterile Packaging Integrity testing is carried out in accordance with:

- ASTM F1980: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169: Standard Practice for Performance Testing of Shipping Containers and Systems

	• ASTM F1886/F1886M: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection • ASTM F2096: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (Test Method B – Procedure for Porous Packaging.) Seal Strength tests performed based on: • EN 868-5: Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods and • ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials Test reports that verify the Electromagnetic Compatibility and Electricial 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. Similar requirements and test methods are used in the bench test for the predicate device, which supports the determination of substantial equivalence. The line extension Ambu® aScope™ 4 RhinoLaryngo Slim and predicate device have the same intended use fundamental technology and there are no significant differences that raise different questions of safety and effectiveness.
Performance Data – Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate and reference devices it has been concluded that the functionality and intended use of Ambu® aScope™ 4 RhinoLaryngo Slim is substantially equivalent to the predicate device. It is concluded that Ambu® aScope™ 4 RhinoLaryngo Slim is as safe and as effective and perform as well as the predicate device.