March 28, 2018

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

Re: K173727
Trade/Device Name: Ambu® aScope™ 3 Slim 3.8/1.2 and Ambu® aScope™ 4 Broncho Slim 3.8/1.2; Ambu® aScope™ 3 Regular 5.0/2.2 and Ambu® aScope™ 4 Broncho Regular 5.0/2.2; Ambu® aScope™ 3 Large 5.8/2.8 and Ambu® aScope™ 4 Broncho Large 5.8/2.8; Ambu® aView Monitor
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 23, 2018
Received: February 26, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K173727

Device Name
Ambu® aScope™ 3; Ambu® aScope™ 4 Broncho; Ambu® aView™ Monitor

Indications for Use *(Describe)*

The aScope 3 and aScope 4 Broncho endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The aScope 3 system and aScope 4 Broncho system are for use in a hospital environment.

The aScope 3 and aScope 4 Broncho are single-use devices designed for use in adults. They have been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:

	Minimum ETT inner diameter	Minimum DLT size	EA minimum working channel width
aScope 3 Slim and aScope 4 Broncho Slim	5.0 mm	35 Fr	Up to 1.2 mm
aScope 3 Regular aScope 4 Broncho Regular	6.0 mm	41 Fr	Up to 2.0 mm
aScope 3 Large aScope 4 Broncho Large	7.0 mm	-	Up to 2.6 mm

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 510(k) has been prepared in accordance with 21 CFR 807.92.

Submitter

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Date Summary Prepared

December 4, 2017

Device Trade Name

Ambu® aScope™ 3 Slim 3.8/1.2
Ambu® aScope™ 3 Regular 5.0/2.2
Ambu® aScope™ 3 Large 5.8/2.8
Ambu® aScope™ 4 Broncho Slim 3.8/1.2
Ambu® aScope™ 4 Broncho Regular 5.0/2.2
Ambu® aScope™ 4 Broncho Large 5.8/2.8
Ambu® aView™ Monitor

Device Common Name

Flexible Bronchoscope

Device Classification

Bronchoscope (flexible or rigid) and accessories
Product Codes: EOQ
21 CFR 874.4680
Class II

Legally Marketed devices to which the device is substantially equivalent

	Manufacturer	Trade Name	510k number
Predicate A+B+C	Ambu A/S	Ambu® aScope™ 3	K161656
Reference D	Vision-Science	BRS-5000 Video Bronchoscope	K091768

Description of the Device

The Ambu® aScope™ 3 system consists of:

- Ambu® aScope™ 3 Slim 3.8/1.2
- Ambu® aScope™ 3 Regular 5.0/2.2
- Ambu® aScope™ 3 Large 5.8/2.8
- Ambu® aView™ Monitor

The Ambu® aScope™ 4 Broncho System

- Ambu® aScope™ 4 Broncho Slim 3.8/1.2
- Ambu® aScope™ 4 Broncho Regular 5.0/2.2
- Ambu® aScope™ 4 Broncho Large 5.8/2.8
- Ambu® aView™ Monitor

Ambu® aScope™ 3 and Ambu® aScope™ 4 Broncho is a sterile single use flexible bronchoscope and Ambu Ambu® aView™ is a reusable monitor.

Ambu® aScope™ 3 and Ambu® aScope™ 4 Broncho endoscopes have 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

The differences between sizes in both the Ambu® aScope™ 3 endoscope and Ambu® aScope™ 4 Broncho endoscope are as follows:

- Distal end outer diameter
- Insertion tube outer diameter
- Working channel inner diameter
- Angulation range

Ambu® aView™ Monitor has the following physical and performance characteristics:

- Displays the image from Ambu® aScope™ 3 endoscope and Ambu® aScope™ 4 Broncho endoscope on the screen
- Can record snapshots or video of image from Ambu® aScope™ 3 and Ambu® aScope™ 4 Broncho endoscope
- Can connect to an external monitor
- Reusable device

Indications for Use

The aScope 3 and aScope 4 Broncho endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The aScope 3 system and aScope 4 Broncho system is for use in a hospital environment.

The aScope 3 system and aScope 4 Broncho system are for use in a hospital environment. The aScope 3 and aScope 4 Broncho are single-use devices designed for use in adults.

They have been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:

	Minimum ETT inner diameter	Minimum DLT size	EA minimum working channel width
aScope 3 Slim and aScope 4 Broncho Slim	5.0 mm	35 Fr	Up to 1.2 mm
aScope 3 Regular aScope 4 Broncho Regular	6.0 mm	41 Fr	Up to 2.0 mm
aScope 3 Large aScope 4 Broncho Large	7.0 mm	-	Up to 2.6 mm

Summary of the technological characteristics in comparison to the predicate and reference devices

Ambu® aScope™ 4 is similar to the predicate and reference devices described in K161656 and K091768.

The product line extension Ambu® aScope™ 4 Broncho are similar to the predicate and reference devices in the following areas:

- They all have the same intended use
- They are all single-use devices delivered sterile
- They are all flexible endoscopes with a maneuverable tip
- They are all video endoscopes with a camera located in the distal tip to provide an image on a separate monitor
- They all use an LED-light source located in the distal tip
- They all have suction functionality
- They all have a working channel for insertion of endoscopic accessories
- They all have the same insertion tube working length
- They all have equivalent inner and outer diameters in their corresponding sizes.

Performance Data –Bench

The following data are described for the product line extension Ambu® aScope™ 4 Broncho System in the premarket notification:

- Declaration of Conformity with the product specific standards ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 594-1
- Performance tests to document the properties of bending angle, endurance and radius of the bending section, the depth of field and clearer image quality design validation test
- Aging Performance Test
- Sterile Packaging Integrity Test
- Electrical Compatibility according to IEC 60601-1-2
- Electrical Safety according to IEC 60601-1 and IEC 60601-2-18

Results: All tests were passed.

Performance Data – Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate and reference devices it is concluded that the functionality and intended use of Ambu® aScope™ 3, Ambu® aScope™ 4 Broncho and Ambu® aView™ Monitor is equivalent to the predicate and reference devices. It is concluded that Ambu® aScope™ 3, Ambu® aScope™ 4 Broncho and Ambu® aView™ Monitor are as safe and effective and perform as well as or better (regarding distal bending section/angulation range, depth of field and exposure for clearer visibility of the image) than the chosen legally marketed predicate and reference devices.