DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 1, 2016

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

Re: K161656
Trade/Device Name: Ambu Ascope 3 Regular 5.0/2.2, Ambu Ascope 3 Slim 3.8/1.2, Ambu Ascope 3 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: August 5, 2016
Received: August 8, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161656

Device Name

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

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

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

The aScope 3 is a single-use device designed for use in adults. It has been clinically evaluated for the following minimum endotracheal tubes (ETT) and double lumen tubes (DLT) sizes:

	Minimum ETT inner diameter	Minimum DLT size
aScope 3 Slim 3.8/1.2	5.0 mm	37 Fr
aScope 3 Regular 5.0/2.2	6.0 mm	41 Fr
aScope 3 Large 5.8/2.8	7.0 mm	-

Endoscopic accessories designed for a minimum working channel width up to 1.2 mm can be used with the aScope 3 Slim 3.8/1.2.
Endoscopic accessories designed for a minimum working channel width up to 2.0 mm can be used with the aScope 3 Regular 5.0/2.2.
Endoscopic accessories designed for a minimum working channel width up to 2.6 mm can be used with the aScope 3 Large 5.8/2.8.

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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Section 5 510(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

June 7, 2016

Device Trade Name

Ambu® aScope™ 3 Regular 5.0/2.2
Ambu® aScope™ 3 Slim 3.8/1.2
Ambu® aScope™ 3 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
A+B:	Ambu A/S	Ambu® aScope 3™ 5.0/2.2, Ambu® aScope™ 3 Slim 3.8/1.2 and Ambu® aView	K130845
C:	Olympus Corporation	Olympus BF-1TH190 Video Bronchoscope	K121959

Description of the Device

The Ambu® aScope™ 3 System consists of:

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

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

Ambu® aScope™ 3 endoscopes 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

The differences between the Ambu® aScope™ 3 endoscope sizes 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 on the screen.
- Can record snapshots or video of image from Ambu® aScope™ 3 endoscope.
- Can connect to an external monitor.
- Reusable device

Indications for Use

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

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

The aScope 3 is a single-use device designed for use in adults. It has been clinically evaluated for the following minimum endotracheal tubes (ETT) and double lumen tubes (DLT) sizes:

	Minimum ETT inner diameter	Minimum DLT size
aScope 3 Slim 3.8/1.2	5.0 mm	37 Fr
aScope 3 Regular 5.0/2.2	6.0 mm	41 Fr
aScope 3 Large 5.8/2.8	7.0 mm	-

	Endoscopic accessories designed for a minimum working channel width up to 1.2 mm can be used with the aScope 3 Slim 3.8/1.2. Endoscopic accessories designed for a minimum working channel width up to 2.0 mm can be used with the aScope 3 Regular 5.0/2.2. Endoscopic accessories designed for a minimum working channel width up to 2.6 mm can be used with the aScope 3 Large 5.8/2.8.

Summary of the technological characteristics in comparison to the predicate devices	Ambu® aScope™ 3 Regular, Ambu® aScope™ Slim and Ambu® aView™ are similar to predicate devices described in K130485.
	
	The product line extension Ambu® aScope™ 3 Large 5.8/2.8 is similar to the predicate devices in the following areas:
	
	• They are all flexible endoscopes with a maneuverable tip
	• Predicate A and B has same intended use. Reference C has a similar intended use.
	• Predicate A and B are single-use device, which are delivered sterile.
	• Predicate A and B uses a LED-light source located at the tip of the endoscopes.
	• They are all video endoscopes with a camera located in the distal tip to provide an image on a separate monitor.
	• They all have the same insertion tube working length.
	• They all have suction functionality. Predicate A and B possess a suction port equivalent to aScope 3 Large.
	• The aScope 3 Large inner and outer diameters are equivalent to the reference device:
	  o Reference C have the same distal end outer diameter as aScope 3 Large. Predicate A and B have a smaller diameter.
	  o Reference C has the same working channel inner diameter as aScope 3 Large. Predicate A and B have a smaller working channel inner diameter

Performance Data –Bench	The following data are described for the product line extension Ambu® aScope™ 3 Large 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 and endurance of the bending section • 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 devices it has been concluded that the functionality and intended use of Ambu® aScope™ 3 Regular 5.0/2.2, Ambu® aScope™ 3 Slim 3.8/1.2, Ambu® aScope™ 3 Large 5.8/2.8 and Ambu® aView™ Monitor is equivalent to the predicate devices. It is concluded that Ambu® aScope™ 3 Regular 5.0/2.2, Ambu® aScope™ 3 Slim 3.8/1.2, Ambu® aScope™ 3 Large 5.8/2.8 and Ambu® aView™ Monitor are as safe and effective and perform as well as or better than the chosen legally marketed predicate devices.