June 17, 2021

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

Re: K210883
Trade/Device Name: aScope 4 Broncho Regular Sampler Set 5.0/2.2, aScope 4 Broncho Large Sampler Set 5.8/2.8
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 17, 2021
Received: May 18, 2021

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 Shu-Chen Peng
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210883

Device Name
Ambu® aScope™ 4 Broncho Regular Sampler Set 5.0/2.2
Ambu® aScope™ 4 Broncho Large Sampler Set 5.8/2.8

Indications for Use *(Describe)*
aScope 4 Broncho Sampler Set consists of sterile, single use, flexible endoscope with sample containers (aScope BronchoSampler), intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope BronchoSampler is designed as an add-on to aScope 4 Broncho during Bronchial Alveolar Lavage (BAL) or Bronchial Wash (BW) procedure which enables aspiration and collection of fluid sample(s) from the bronchial or alveolar part of the lung.
It is designed for use in adults and intended for use in a hospital environment.
It is intended to provide visualization via Ambu Displaying Unit.

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

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	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	March, 23, 2021
510(k) no.	K210883
Device Trade Name	Ambu® aScope™ 4 Broncho Regular Sampler Set 5.0/2.2 Ambu® aScope™ 4 Broncho Large Sampler Set 5.8/2.8
Device Common Name	Flexible Endoscope and Specimen Sampling System – Single Use
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:	Ambu A/S	Ambu® aScope™ 4 Broncho Regular and Large	K173727

Description of the Device

The Ambu® aScope™ 4 Broncho Sampler Set consists of:

- aScope 4 Regular/Large endoscope
- aScope BronchoSampler ™

Ambu® aScope™ 4 Broncho Sampler Set consists of sterile, single use, flexible endoscope with sample containers (aScope BronchoSampler), intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope BronchoSampler is designed as an add-on to aScope 4 Broncho during Bronchial Alveolar Lavage (BAL) or Bronchial Wash (BW) procedure which enables aspiration and collection of fluid sample(s) from the bronchial or alveolar part of the lung. Both of the aScope 4 Broncho and BronchoSampler are already marketed separately.

Ambu® aScope™ 4 Broncho Sampler Set 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
- Enables aspiration and sample collection in BAL and BW procedures

<u>The differences between the endoscope sizes are as follows:</u>

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

Indications for Use

Ambu® aScope™ 4 Broncho Sampler Set consists of sterile, single use, flexible endoscope with sample containers (aScope BronchoSampler), intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope BronchoSampler is designed as an add-on to aScope 4 Broncho during Bronchial Alveolar Lavage (BAL) or Bronchial Wash (BW) procedure which enables aspiration and collection of fluid sample(s) from the bronchial or alveolar part of the lung.

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

It is intended to provide visualization via Ambu Displaying Unit.

Summary of the technological characteristics in comparison to the predicate devices

The endoscope of Ambu® aScope™ 4 Broncho Sampler Set is similar to the predicate device A in the following areas:

- 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 displaying unit.
- They all provide illumination from the distal tip.
- They all have suction functionality
- They all have the same insertion tube working length

	• They all have equivalent inner and outer diameters in their corresponding sizes. The endoscope of Ambu® aScope™ 4 Broncho Sampler Set differs from the predicate device A in the following areas: • Bronchosampler is added in Ambu® aScope™ 4 Broncho Sampler Set which can be attached to the handle of the endoscope.
Performance Data –Bench	The following data are described for the product line extension Ambu® aScope™ 4 Broncho Sampler Set in the premarket notification: • Declaration of Conformity with the product specific standards ISO 8600-1, ISO 8600-3 and ISO 8600-4 • Aging performance test • Sterile Packaging Integrity • Electromagnetic Compatibility according to IEC 60601-1-2 • Electrical Safety according to IEC 60601-1 and IEC 60601-2-18. • Performance test for Single-use receptacles according to EN 14254 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 Broncho Sampler Set is substantially equivalent to the predicate device. It is concluded that Ambu® aScope™ 4 Broncho Sampler Set is as safe and as effective and performs as well as the predicate device.