September 20, 2023

Ambu A/S
% Sanjay Parikh
Director, QA/RA
Ambu Inc.
6721 Columbia Gateway Drive, Suite 200
Columbia, Maryland 21046

Re: K232582
Trade/Device Name: Ambu® aScope™ 5 Broncho 4.2/2.2 Sampler Set
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 25, 2023
Received: August 25, 2023

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232582

Device Name
Ambu® aScope™ 5 Broncho 4.2/2.2 Sampler Set

Indications for Use *(Describe)*

Ambu® aScope™ 5 Broncho Sampler Set is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.

Ambu® aScope™ 5 Broncho Sampler Set is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of endotherapy instruments via its working channel.

Ambu® aScope™ 5 Broncho Sampler Set enables aspiration and collection of fluid samples.

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.

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) summary has been prepared in accordance with 21 CFR 807.92.

Submitter

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Contact Person

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Date Summary Prepared

August 22, 2023

Device Trade Name

Ambu® aScope™ 5 Broncho 4.2/2.2 Sampler Set

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	510(k) number
Predicate	Ambu A/S	Ambu® aScope™ 5 Broncho 4.2/2.2	K230428

Description of the Device

The Ambu® aScope™ 5 Broncho Sampler Set consists of:

- Ambu® aScope™ 5 Broncho endoscope
- Two Sample Containers (Ambu® aScope BronchoSampler™ 60 SC)
- Suction Connection Tube (SCT)
- Bronchoscope Attachment Part (BAP)
- 2 Luer lock adapters (Introducers)

Ambu® aScope™ 5 Broncho is currently being sold on its own as a sterile, single use, flexible endoscope intended for endoscopic procedures and examination within the airways and tracheobronchial tree (K230428).

The Ambu® aScope BronchoSampler™ 60 SC is a 510(k)-exempt device, also sold alone under the trade name Ambu® aScope BronchoSampler™ SC.

The combination of the Ambu® aScope BronchoSampler™ 60 SC, the Bronchoscope Attachment Part (BAP) and Suction Connection Tube (SCT) is collectively referred to as the BronchoSampler 60.

BronchoSampler 60 is a sterile, single-use medical component designed as an accessory to aScope™ 5 Broncho single-use endoscopes. It is used for fluid sampling in bronchoscopic procedures such as 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.

The Ambu® aScope BronchoSampler™ 60 SC can be removed and replaced by the user to support multiple samples being taken during the same procedure.

The Bronchoscope Attachment Part (BAP) is inserted into the suction pathway between the Ambu® aScope™ 5 Broncho endoscope and the vacuum source. It functions to maintain the connections and the controls for the suction pathway and the Ambu® aScope BronchoSampler™ 60 SC, where the aspirated sample is stored.

The Suction Connection Tube (SCT) facilitates connection to suction tubing.

The Ambu® aScope BronchoSampler™ 60 SC plus an additional Sample Container, BAP, SCT and two introducers will be packaged

and sterilized together with Ambu® aScope™ 5 Broncho endoscope to form a self-contained set, the Ambu® aScope™ 5 Broncho Sampler Set.

Ambu® aScope™ 5 Broncho Sampler Set has the following physical and performance characteristics:

- Maneuverable Ambu® aScope™ 5 Broncho endoscope tip controlled by the user
- Flexible Ambu® aScope™ 5 Broncho endoscope insertion cord
- Camera and LED light source at the distal tip of the Ambu® aScope™ 5 Broncho endoscope
- Sterilized by Ethylene Oxide
- For single use
- Enables aspiration and sample collection in BAL and BW procedures

Indications for Use

Ambu® aScope™ 5 Broncho Sampler Set is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.

Ambu® aScope™ 5 Broncho Sampler Set is intended to provide visualization via a compatible Ambu displaying unit and to allow passing of endotherapy instruments via its working channel.

Ambu® aScope™ 5 Broncho Sampler Set enables aspiration and collection of fluid samples.

Summary of the technological characteristics in comparison to the predicate devices

The Ambu® aScope™ 5 Broncho endoscope in the Ambu® aScope™ 5 Broncho Sampler Set is identical to the predicate cleared under K230428.

Ambu® aScope™ 5 Broncho Sampler Set differs from the predicate in the following areas:
The exempt device, Ambu® aScope BronchoSampler™ 60 SC, BAP, SCT and two introducers are added to the Ambu® aScope™ 5 Broncho endoscope.
Ambu® aScope BronchoSampler™ 60 SC, BAP, SCT and two introducers are packaged and sterilized together with aScope™ 5 Broncho to form a self-contained set, the Ambu® aScope™ 5 Broncho Sampler Set.

Performance Data – Bench	Bench testing has been performed in accordance with ISO 14971 as Design Verification of those Design Input requirements that are specified as risk control measures for those risks arising from the addition of sampling functionality to the endoscope. A summary of the activities carried out to verify the additional requirements and identified risks arising from the risk control measures are as follows: • Transportation testing • Packaging testing • Suction Testing • Connectivity testing • Tests for basic function of BronchoSampler 60 • Biological evaluation • Sterilization Validation Result: All requirements are verified successfully.
Performance Data – Clinical	Not applicable.
Conclusion	The Ambu® aScope™ 5 Broncho Sampler Set has the same intended use and indications for use, and similar technological characteristics and principles of operation as the predicate device. The minor differences between the Ambu® aScope™ 5 Broncho Sampler Set and its predicate device, namely the addition of the 510(k)-exempt device Ambu® aScope BronchoSampler™ 60 SC and the BAP, SCT and introducers do not raise any new concerns regarding safety or effectiveness. It is concluded that Ambu® aScope™ 5 Broncho Sampler Set is substantially equivalent to its predicate device.