January 12, 2023

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

Re: K223782
Trade/Device Name: Ambu aScope 5 Broncho HD 5.6/2.8 Sampler Set, Ambu aScope 5 Broncho HD 5.0/2.2 Sampler Set
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 12, 2022
Received: December 16, 2022

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,

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)*
K223782

Device Name
Ambu® aScope™ 5 Broncho HD 5.6/2.8 Sampler Set
Ambu® aScope™ 5 Broncho HD 5.0/2.2 Sampler Set

Indications for Use *(Describe)*
Ambu® aScope™ 5 Broncho HD Sampler Set is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.

Ambu® aScope™ 5 Broncho HD 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 HD 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.

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

Submitter	Ambu A/S Baltorpbakken 13 2750 Ballerup Denmark Tel.: +45 7225 2000 Fax.: +45 7225 2050
Contact Person	Name: Kristian Moltved Job Title: Associate Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, 2750 Ballerup Telephone number: +45 7225 2116 Fax number: +45 7225 2050
Date Summary Prepared	December 12, 2022
Device Trade Name	Ambu® aScope™ 5 Broncho HD 5.6/2.8 Sampler Set Ambu® aScope™ 5 Broncho HD 5.0/2.2 Sampler Set
Device Common Name	Flexible Endoscope and Specimen Sampling System – Single Use
Device Classification	*Ambu® aScope™ 5 Broncho HD Sampler Set*: 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	Predicate: Ambu A/S, Ambu® aScope™ 5 Broncho HD, K220606

Description of the Device

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

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

Ambu® aScope™ 5 Broncho HD 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.

The *Ambu® BronchoSampler™ 60 SC* is a sterile, single-use medical device designed as an accessory to aScope 5 Broncho HD single-use endoscopes. It enables aspiration and collection of fluid samples.

The *Ambu® BronchoSampler™ 60 SC* will be sold alone as an add-on to *aScope 5 Broncho HD* and as a part in the *Ambu® aScope™ 5 Broncho HD Sampler Set*.

The *Ambu® BronchoSampler™ 60 SC* achieves its function by being inserted into the suction pathway between the endoscope and the vacuum source.

The Sample Container *Ambu® 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 HD* endoscope and the vacuum source. It functions to maintain the connections and the controls for the suction pathway and the *Ambu® BronchoSampler™ 60 SC*, where the aspirated sample is stored.

The Suction Connection Tube (SCT) facilitates connection to suction tubing having end connectors of the male type, instead of the more typical female type.

The *Ambu® BronchoSampler™ 60 SC* plus an additional Sampler Container, *BAP, SCT* and two *introducers* will be packaged and sterilized together with a *aScope 5 Broncho HD* endoscope to form a self-contained set, the *aScope 5 Broncho HD Sampler Set*.

There will be two sets, corresponding to the two sizes of *aScope 5 Broncho HD*:

a. Ambu® aScope 5 Broncho HD 5.6/2.8 Sampler Set
b. Ambu® aScope 5 Broncho HD 5.0/2.2 Sampler Set

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

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

The following characteristic of the endoscope varies between sizes:

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

Indications for Use	*Ambu® aScope™ 5 Broncho HD Sampler Set* is intended for endoscopic procedures and examination within the airways and tracheobronchial tree. *Ambu® aScope™ 5 Broncho HD 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 HD Sampler Set enables aspiration and collection of fluid samples.*
Summary of the technological characteristics in comparison to the predicate device	The *Ambu® aScope™ 5 Broncho HD* endoscope in the *Ambu® aScope™ 5 HD Broncho Sampler Set* is identical to the predicate. *Ambu® aScope™ 5 Broncho HD Sampler Set* differs from the predicate in the following areas: • *Ambu® aScope™ BronchoSampler 60 SC, BAP, SCT* and two *introducers* are added to the *Ambu® aScope™ 5 Broncho HD* endoscope. • *Ambu® aScope™ BronchoSampler 60 SC, BAP, SCT* and two *introducers* are packaged and sterilized together with *aScope 5 Broncho HD* endoscopes to form a self-contained set, the *Ambu® aScope™ 5 Broncho HD Sampler Set*.
Performance Data –Bench	Performance tests related to the modifications was performed to document the following properties of the modification to *Ambu® aScope™ 5 Broncho HD*. In addition to the non-clinical performance testing documented for the *Ambu® aScope™ 5 Broncho HD* (K220606), additional 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 table of this special 510(k) cross references these additional risks, documented in the Product Risk Evaluation for the *Ambu® aScope™ 5 Broncho Sampler Set*, with the risk control measures and the subsequent verification results.

	A summary of the methods 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. It is concluded that *Ambu® aScope™ 5 Broncho Sampler Set* is substantial equivalent to its predicate device.