July 25, 2022

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

Re: K220606
Trade/Device Name: Ambu aScope 5 Broncho HD 5.6/2.8, Ambu aScope 5 Broncho HD 5.0/2.2, Ambu aBox 2
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 21, 2022
Received: June 22, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220606

Device Name
Ambu® aScope™ 5 Broncho HD 5.0/2.2
Ambu® aScope™ 5 Broncho HD 5.6/2.8
Ambu® aBox™ 2

Indications for Use *(Describe)*
Ambu® aScope™ 5 Broncho HD is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.
Ambu® aScope™ 5 Broncho HD is intended to provide visualization via a compatible Ambu® displaying unit, and to allow passing endotherapy instruments via its working channel.

The aBox™ 2 is intended to display live imaging data from compatible Ambu visualization devices

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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K220606 510(k) Summary

This traditional 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: Senior 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, 01, 2022	
Device Trade Name	Ambu® aScope™ 5 Broncho HD 5.0/2.2 Ambu® aScope™ 5 Broncho HD 5.6/2.8 Ambu® aBox™ 2	
Device Common Name	Endoscopy system	
Device Classification	Ambu® aScope™ 5 Broncho HD: Bronchoscope (flexible or rigid) and accessories Product Codes: EOQ 21 CFR 874.4680 Class II	Ambu® aBox™ 2: Bronchoscope (flexible or rigid) and accessories Product Codes: EOQ 21 CRF 876.4680 Class II
Legally Marketed devices to which the device is substantially equivalent	<u>Predicate Device A:</u> Ambu® aScope™ 4 Broncho Regular and Large K173727 <u>Reference Device B:</u> OLYMPUS EVIS EXERA III Bronchovideoscope BF-H190 K121959	<u>Predicate Device:</u> OLYMPUS EXERA II Light Source (CLV-180) and Video System Center (CV-180) K061313

Description of the Device

The Ambu aScope 5 Broncho HD System is a combination of the displaying unit, Ambu aBox 2, and a compatible Ambu endoscope, the Ambu aScope 5 Broncho HD 5.0/2.2 or the Ambu aScope 5 Broncho HD 5.6/2.8

The Ambu aScope 5 Broncho HD endoscopes are single-use endoscopes designed to be used with Ambu displaying units, endotherapy instruments and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The insertion portion is inserted into the patient airway through the mouth, nose, or a tracheostomy. It is lubricated with a water-soluble medical grade lubricant to ensure the lowest possible friction when inserted into the patient. There is a working channel system within the endoscope for use with endotherapy instruments. An introducer (luer lock adaptor), which is supplied together with the endoscope, can be attached to the working channel port during use. Suctioning of blood, saliva, and mucus from the airway is possible through the suction system.

Ambu aScope 5 Bronco HD features an integrated camera module, with built-in dual LED illumination. The image module provides a cropped 800x800 Pixels signal from the 1280x800 (1 megapixel) sensor.

The Ambu aBox 2, also referred to as displaying unit, is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The product consists of a base unit with a 12.8" LCD screen mounted on the top. The device is powered by an integrated power supply and comes with country specific power cables.

Ambu® aBox 2 displaying unit has the following physical and performance characteristics:

- Displays the image from Ambu® aScope™ 5 Broncho HD endoscope on the screen.
- Can record snapshots or video of image from Ambu® aScope™ 5 Broncho HD endoscope.
- Can connect to an external monitor.
- Reusable device

Intended use/Indications for use

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

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

The aBox™ 2 is intended to display live imaging data from compatible Ambu visualization devices.

Summary of the technological characteristics in comparison to the predicate devices

The Ambu® aScope™ 5 Broncho HD and the predicate device, Ambu® aScope™ 4 Broncho are single-use devices.
Both devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord & distal end and insertion portion length.
Furthermore, they have the following same technical characteristics:

- Both have maneuverable tip controlled by the user
- Both have flexible insertion cord
- Both have camera and LED light source at the distal tip
- Both are sterilized by Ethylene Oxide
- Both are single use devices
- Both devices enable aspiration and sample collection in BAL and BW procedures

The differences between the Ambu® aScope™ 5 Broncho HD and the predicate device are as follows:

- Ambu® aScope™ 5 Broncho HD has a rotary function as the reference device
- Ambu® aScope™ 5 Broncho HD has two endoscope buttons as the reference device

The Ambu® aBox™ 2 and its predicate device have the following same technological characteristics:

- Both are video processors displaying live video-imaging data of the connected visualization device to a monitor.
- Both provide video output formats, recording and data storage and data transport functions.
- Both share certain technical functionalities as brightness control, image contrast and sharpness adjustment and zoom function.
- Contrary to the predicate device, the Ambu® aBox™ 2 is portable and has an integrated monitor, therefore, an external monitor is not necessary.

Performance Data –Bench

The following tests to verify the design and evaluate the performance of the Ambu® aScope™ 5 Broncho HD system were done.

Performance requirements evaluated in accordance with the ISO 8600 series.

- ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements
- ISO 8600-3:2019 Optics and optical instruments – Medical endoscopes and certain accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes – Medical endoscopes and endotherapy devices – Determination of maximum width of insertion portion
- ISO 8600-5:2005 Optics and photonics – Medical endoscopes and endotherapy devices – Part 5: Determination of optical resolution of rigid endoscopes with optics
- ISO 8600-6:2020 Optics and photonics - Medical endoscopes and endotherapy devices - Part 6: Vocabulary

Result: All tests passed.

Performance test reports to document the following properties:

- Field of view
- Direction of view
- Depth of Field
- Insertion cord dimensions
- Suction performance
- Bending performance
- Duration of use

Result: All tests passed.

Performance test reports to document shelf life. Tests were performed on finished, sterilized, and aged products:

- Performance tests
- Sterile packaging integrity

Result: All tests passed.

Biocompatibility according to ISO 10993-1 including cytotoxicity, irritation, sensitization, and systemic toxicity:

- Cytotoxicity (ISO 10993-5)
- Irritation (ISO 10993-23)
- Sensitization (ISO 10993-10)
- Systemic toxicity test (ISO 10993-11)

Result: All tests passed.

Test reports that verify the Electromagnetic Compatibility and Electrical Safety:

- Electromagnetic Compatibility in compliance with IEC 60601-1-2
- Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18

Result: All tests passed.

In all instances, the Ambu® aScope™ 5 Broncho HD system performed as expected and met the test specifications set.

Conclusion

The Ambu® aScope™ 5 Broncho HD system, consisting of Ambu® aScope™ 5 Broncho HD and Ambu® aBox™ 2, has the same intended use and indications for use, and similar technological characteristics and principles of operation as their predicate devices.

The minor technological differences between the Ambu® aScope™ 5 Broncho HD system and its predicate devices raise no new concerns regarding safety or effectiveness.

Therefore, it is concluded that Ambu® aScope™ 5 Broncho HD system consisting of Ambu® aScope™ 5 Broncho HD 5.0/2.2,
Ambu® aScope™ 5 Broncho HD 5.6/2.8 and
Ambu® aBox™ 2 is substantial equivalent to its predicate devices.