August 10, 2023

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

Re: K230428
Trade/Device Name: Ambu® aScope™ 5 Broncho 2.7/1.2, Ambu® aScope™ 5 Broncho 4.2/2.2, 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: July 10, 2023
Received: July 11, 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: K230428

Device Name
Ambu® aScope™ 5 Broncho 4.2/2.2
Ambu® aScope™ 5 Broncho 2.7/1.2
Ambu® aBox™ 2

Indications for Use *(Describe)*
aScope™ 5 Broncho is intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope™ 5 Broncho is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of 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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510(k) Summary – Ambu® aScope™ 5 Broncho System

This 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: Karina Matthiesen Job Title: Senior Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, 2750 Ballerup, Denmark Email: kama@ambu.com Tel.: +45 7225 2000
Date Summary Prepared	August 10, 2023
Device Trade Name	Ambu® aScope™ 5 Broncho 2.7/1.2 Ambu® aScope™ 5 Broncho 4.2/2.2 Ambu® aBox™ 2
Device Common Name	Endoscopy system
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	Ambu® aScope™ 5 Broncho: Predicate Device A (K220606): Ambu® aScope™ 5 Broncho HD 5.0/2.2, Ambu® aScope™ 5 Broncho HD 5.6/2.8 Reference Device B (K173727): Ambu® aScope™ 4 Broncho Slim and Regular Ambu® aBox™ 2: Predicate Device A (K220606): Ambu® aBox™ 2

Description of the Device	The Ambu® aScope™ 5 Broncho System is a combination of a displaying unit, the Ambu® aBox™ 2, and a compatible endoscope, Ambu® aScope™ 5 Broncho. Ambu® aScope™ 5 Broncho is a sterile, single-use flexible bronchoscope designed to conduct endoscopic procedures and examination of the airways and tracheobronchial tree. The endoscope is available in two size configurations: Ambu® aScope™ 5 Broncho 4.2/2.2 and Ambu® aScope™ 5 Broncho 2.7/1.2. Apart from the size, the endoscopes share a similar design. The insertion portion is inserted into the patient airway through the mouth, nose, endotracheal tube, tracheostomy tube, etc. There is a working channel system within the endoscope for use with endotherapy instruments or instillation of fluids. An introducer (luer lock adaptor), which is supplied together with the endoscopes, can be attached to the working channel port during use. Suctioning of blood, saliva, and mucus from airway is possible through the suction system. Ambu® aScope™ 5 Broncho features an integrated camera module with built-in dual LED illumination. The image module provides a cropped 400x400 pixels signal from the 160 Kpixel 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. The Ambu® aBox™ 2 has the following physical and performance characteristics: • Displays the image from Ambu® aScope™ 5 Broncho endoscope on the screen • Can record snapshots or video of image from Ambu® aScope™ 5 Broncho endoscope • Can connect to an external monitor • Is a reusable device
Intended Use/Indications for Use	aScope 5 Broncho is intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope 5 Broncho is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of 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

Ambu® aScope™ 5 Broncho and the predicate endoscope, Ambu® aScope™ 5 Broncho HD, are both sterile, single-use flexible bronchoscopes. Furthermore, they share the following technological characteristics:

- Both devices have a maneuverable tip controlled by the user.
- Both devices have a camera and LED light source located in the distal tip.
- Both devices have a rotary function enabling the orientation of camera and working channel in relation to the bronchoscope handle to be altered.
- Both devices have two endoscope buttons to communicate with the displaying unit.
- Both devices have a suction system activated by a suction button.
- Both devices are sterilized by Ethylene Oxide.
- Both devices are compatible with the displaying unit Ambu® aBox™ 2.

Ambu® aScope™ 5 Broncho has the same handle as the predicate device, but the insertion portion differs in the following ways:

- The outer diameter of the insertion portion is smaller than for the predicate device.
- The working channel is smaller than for the predicate device.
- Due to the smaller endoscope tip, the camera technology differs from the predicate e.g., lower resolution.

The Ambu® aBox™ 2 and the predicate displaying unit share the following 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 technical functionalities such as brightness control, image contrast and sharpness adjustment and zoom function.
- Both are portable and have an integrated monitor in addition to the possibility to connect to an external monitor.

The differences between the aBox 2 and the predicate device are as follows:

- The predicate device aBox 2 is not compatible with the applicant device Ambu aScope 5 Broncho

Performance Data – Bench

Performance requirements were evaluated in accordance with the ISO 8600 series:

- ISO 8600-1 Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements
- ISO 8600-3 Endoscopes – Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics

- ISO 8600-4 Endoscopes – Medical endoscopes and endotherapy devices – Part 4: Determination of maximum width of insertion portion

The following tests were performed to verify/validate the design and evaluate the performance of the Ambu® aScope™ 5 Broncho System:

- Verification tests including:
  - Insertion portion dimensions
  - Bending performance
  - Suction performance
  - Duration of use
- Optical performance tests including:
  - Field of view
  - Direction of view
  - Depth of field*
  - Resolution*
  - Color performance*
  - Image intensity uniformity*
  - Geometric distortion*
- Photobiological safety according to IEC 62471
- Transportation study
- Sterilization validation according to ISO 11135
- Stability study to document shelf life
  - Performance tests
  - Sterile packaging integrity
- Biocompatibility according to ISO 10993-1 including tests for:
  - Cytotoxicity (ISO 10993-5)
  - Irritation (ISO 10993-23)
  - Sensitization (ISO 10993-10)
- Electrical Safety and performance according to IEC 60601-1 and IEC 60601-2-18
- Electromagnetic Compatibility according to IEC 60601-1-2

The camera technology of Ambu® aScope™ 5 Broncho differs from that of the predicate device, however, the different technological characteristics do not raise different questions of safety or effectiveness. The safety and effectiveness of the applicant device was ensured by comparing the results of the optical performance tests marked with * to the reference device, Ambu® aScope™ 4 Broncho, thereby demonstrating substantial equivalence.

Overall, the Ambu® aScope™ 5 Broncho System performed as expected and met the test specifications set.

Conclusion	The Ambu® aScope™ 5 Broncho System, consisting of Ambu® aScope™ 5 Broncho and Ambu® aBox™ 2, has the same intended use/indications for use and similar technological characteristics and principles of operation as the predicate device. The minor technological differences between Ambu® aScope™ 5 Broncho System and its predicate device do not raise any different questions regarding safety or effectiveness. Therefore, it is concluded that the Ambu® aScope™ 5 Broncho System is substantially equivalent to the predicate device.