January 4, 2024

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

Re: K233671
Trade/Device Name: Ambu® aScope™ 5 Broncho 4.2/2.2; Ambu® aScope™ 5 Broncho 2.7/1.2; Ambu® aView™ 2 Advance
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 15, 2023
Received: December 5, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233671

Device Name

Ambu® aScope™ 5 Broncho 4.2/2.2;
Ambu® aScope™ 5 Broncho 2.7/1.2;
Ambu® aView™ 2 Advance

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 Ambu® aView™ 2 Advance 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

Prepared on: 2023-11-15

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ambu® aScope™ 5 Broncho 4.2/2.2; Ambu® aScope™ 5 Broncho 2.7/1.2; Ambu® aView™ 2 Advance
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code	EOQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230428	Ambu® aScope™ 5 Broncho 4.2/2.2, Ambu® aScope™ 5 Bronch	EOQ
K223299	Ambu® aView™ 2 Advance	EOQ

Device Description Summary

21 CFR 807.92(a)(4)

The Ambu® aScope™ 5 Broncho System is a combination of an endoscope, Ambu® aScope™ 5 Broncho, and a compatible displaying unit, Ambu® aView™ 2 Advance.

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® aView™ 2 Advance, also referred to as a displaying unit, is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The product consists of a 12.8" LCD screen. The device is powered through a Lithium-ion (Li-ion) battery or a separate power adapter.

Ambu® aView™ 2 Advance displaying unit has the following physical and performance characteristics:
• Displays the image from the 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.
• Reusable device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 Ambu® aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use / indications for use are the same as for the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

Ambu® aScope™ 5 Broncho is identical to its predicate device (Ambu® aScope™ 5 Broncho submitted in K230428); the only difference is that the subject device is compatible with an additional displaying unit, Ambu® aView™ 2 Advance.

Ambu® aView™ 2 Advance was cleared for use with Ambu® aScope™ 5 Broncho HD in K223299. Equivalent to the bronchoscope subject to this 510(k), the main difference between the predicate and the subject aView 2 Advance is the additional compatibility to Ambu® aScope™ 5 Broncho. There have been no significant changes to the technological characteristics of the device since the submission of K223299.

The differences do not raise any new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

In addition to the performance testing described in the original 510(k)s (K223299 and K230428), additional testing has been performed to address the risks associated with the additional compatibility and to support substantial equivalence to the predicate devices:

• Electrical Safety according to IEC 60601-1 and IEC 60601-2-18
• Electromagnetic Compatibility according to IEC 60601-1-2
• Optical performance tests:
  o Depth of field
  o Resolution
  o Geometric distortion
  o Image intensity uniformity
  o Color performance

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

In conclusion, Ambu® aScope™ 5 Broncho and Ambu® aView™ 2 Advance constituting the Ambu® aScope™ 5 Broncho System, have the same intended use/indications for use and similar technological characteristics as the predicate devices.

The minor technological differences between Ambu® aScope™ 5 Broncho and Ambu® aView™ 2 Advance and their respective predicate device do not raise any different questions regarding safety or effectiveness and have been addressed in the performance testing listed above.

Therefore, it is concluded that the devices in the subject Ambu® aScope™ 5 Broncho System is substantially equivalent to the legally marketed predicates.