



June 1, 2023

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

Re: K223299

Trade/Device Name: Ambu® aScope™ 5 Broncho HD 5.0/2.2, Ambu® aScope™ 5 Broncho HD 5.6/2.8, 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: April 27, 2023

Received: May 1, 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](mailto: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

## Indications for Use

510(k) Number (if known)

**K223299**

Device Name

Ambu® aScope™ 5 Broncho HD 5.0/2.2

Ambu® aScope™ 5 Broncho HD 5.6/2.8

Ambu® aView™ 2 Advance

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 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

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

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<b>Contact Person</b>	Name: Magnus Lynge Job Title: Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup Telephone number: +45 7225 2165	
<b>Date Summary Prepared</b>	April 26 <sup>th</sup> , 2023	
<b>Device Trade Name</b>	Ambu® aScope™ 5 Broncho HD 5.0/2.2 Ambu® aScope™ 5 Broncho HD 5.6/2.8 Ambu® aView™ 2 Advance	
<b>Device Common Name</b>	Endoscopy system	
<b>Device Classification</b>	Ambu® aScope™ 5 Broncho HD: Bronchoscope (flexible or rigid) and accessories Product Codes: EOQ 21 CFR 874.4680 Class II	Ambu® aView™ 2 Advance: Bronchoscope (flexible or rigid) and accessories Product Codes: EOQ 21 CRF 874.4680 Class II
<b>Legally Marketed devices to which the device is substantially equivalent</b>	<u>Predicate Device:</u> Ambu® aScope™ 5 Broncho HD 5.0/2.2 Ambu® aScope™ 5 Broncho HD 5.6/2.8 K220606	<u>Predicate Device:</u> Ambu® aBox™ 2 K220606 <u>Reference Device:</u> Ambu® aView™ K173727

## 510(k) Application – Ambu® aScope™ 5 Broncho HD system

### **Description of the Device**

The Ambu® aScope™ 5 Broncho HD system is a combination of the displaying unit, Ambu® aView™ 2 Advance, 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 bronchoscopes are the same devices as cleared in K220606. The only change is that the bronchoscopes are now also compatible to Ambu® aView™ 2 Advance.

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 Broncho 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® aView™ 2 Advance, 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 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 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 Ambu® aView™ 2 Advance 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 its predicate device, are identical devices. The only difference is, that now the devices are also compatible with the Ambu® aView™ 2 Advance displaying unit.

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

- Both are 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 such as brightness control, image contrast adjustment, live image sharpness adjustment and zoom function.
- Both have a built-in LCD screen that provides live imaging data from the connected supported visualization device. The LCD screens are identical.

The differences between the Ambu® aView™ 2 Advance and the predicate device are as follows:

- Ambu® aView™ 2 Advance can be hung on an IV pole by means of a bracket.
- Ambu® aView™ 2 Advance has both 3G-SDI and HDMI video outputs to allow connection with external medical monitors, whereas the predicate device offers the video output through 3G-SDI and DVI.
- Ambu® aView™ 2 can be powered through a Lithium-ion (Li-ion) battery.

**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.

## 510(k) Application – Ambu® aScope™ 5 Broncho HD system

Performance- and comparison 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
- Image Intensity Uniformity
- Geometrical Distortion
- Resolution
- Color Performance

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® aView™ 2 Advance, 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® aView™ 2 Advance is substantial equivalent to its predicate devices.