April 16, 2024

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

Re: K233886
Trade/Device Name: Ambu® aScope™ Duodeno 2, Ambu® aBox™ 2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT, FET
Dated: December 8, 2023
Received: March 19, 2024

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*
K233886

Device Name
Ambu® aScope™ Duodeno 2, Ambu® aBox™ 2

Indications for Use *(Describe)*
The aScope™ Duodeno 2 is designed to be used with the aBox™2, endoscopic accessories (e.g., biopsy forceps) and other ancillary equipment (e.g., medical grade video monitor) for endoscopy and endoscopic surgery within the duodenum.

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

Prepared on: 2023-12-08

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Mr. Sanjay Parikh
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ambu® aScope™ Duodeno 2; Ambu® aBox™ 2
Common Name	Endoscope and accessories
Classification Name	Duodenoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code	FDT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201098	Ambu® aScope™ Duodeno	FDT
K143153	EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE	FDT
K230332	Ambu® aBox™ 2	FET

Device Description Summary

21 CFR 807.92(a)(4)

The Ambu® aScope™ Duodeno 2 Endoscopy System is a combination of the duodenoscope, Ambu® aScope™ Duodeno 2 and the compatible displaying unit, Ambu® aBox™ 2.

The Ambu® aScope™ Duodeno 2, is a sterile and single-use medical device for endoscopy and endoscopic surgery within the duodenum.

The Ambu® aScope™ Duodeno 2 is a flexible endoscope (duodenoscope) with side viewing optics, deflectable tip and an elevator to control the position of inserted accessories. The angulation of the endoscope tip is controlled via wheels, whereby the angulation can be locked via levers. The elevator (Albarran lever) is also controlled via a lever. Insufflation, suction and rinsing functions are activated via user controls. The product contains remote switches / programmable buttons to activate selected functions of the connected Displaying Unit (Ambu® aBox™ 2). The Ambu® aScope™ Duodeno 2 must be connected to the Ambu® aBox™ 2 to be able to work.

The Ambu® aBox™ 2, also referred to as displaying unit, is a non-sterile, reusable 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:
- Can process and display live imaging data from Ambu® aScope™ Duodeno 2 to a monitor
- Can record, store and transport image data from Ambu® aScope™ Duodeno 2
- Is a portable device with an integrated monitor, and the possibility to connect to an external monitor

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The aScope™ Duodeno 2 is designed to be used with the aBox™ 2, endoscopic accessories (e.g. biopsy forceps) and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the duodenum.

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Ambu® aScope™ Duodeno 2 has the same intended use as the predicate devices.
The Ambu® aBox™ 2 has the same intended use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Ambu® aScope Duodeno 2 and its predicate devices have the following same technological characteristics:
- Both are flexible endoscopes with maneuverable tip, a control section body (handle) and an umbilical cord
- Both control the tip bending via two wheels at the handle and Bowden wires.
- Both provide a working channel and an elevator (Albarran lever)
- Both have same technological characteristics as insertion portion length, working channel diameter, direction of view and bending angels

As the predicate device Ambu® aScope™ Duodeno, the Ambu® aScope Duodeno 2 is a sterile, single-use device and not intended to be reprocessed and is equipped with LEDs for light illumination and does not need an additional light source. Like the predicate device EVIS EXERA II Duodenovideoscope Olympus TJF Type Q180V, the Ambu® aScope™ Duodeno 2 is equipped with a guidewire locking function.

The Ambu® aScope™ Duodeno 2 differs from its predicate devices in some technical specifications including Field of View and Depth of Field. The differences do not introduce issues for safety and performance. The Ambu® aScope™ Duodeno 2 has passed the performance testing.

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 such as brightness control, image contrast and sharpness adjustment as well as zoom function.
- Both devices are portable and have an integrated monitor and offers the possibility of connection to an external monitor.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following tests to verify/validate the design and evaluate the performance of the Ambu® aScope™ Duodeno 2 Endoscopy System were done.
- Geometrical characteristics including
  - Minimum working channel width
  - Length of insertion tube,
  - Maximum insertion portion width,
  - Outer diameter of insertion tube,
  - Bending performance/bending angles,
- Functional performance including

- Insufflation,
- Suction,
- Rinsing,
- Elevator Lever bending capability,
- Guidewire lock performance

• Optical performance/image quality including
- Field of view / Direction of View,
- Depth of field,
- Sharpness across the image,
- Image Intensity Uniformity,
- Color Performance,
- Noise Performance,
- Dynamic Range,
- Geometric distortion

• Photobiological safety according to IEC 62471
• Biocompatibility according to ISO 10993-1 including cytotoxicity, irritation, sensitization
• Sterilization validation according to ISO 11135
• Transport validation including packaging integrity
• Stability study to document shelf life
• Electrical Safety and performance according to IEC 60601-1 and IEC 60601-2-18
• Electromagnetic Compatibility according to IEC 60601-1-2
• System Performance Tests to confirm procedural performance

In all instances, the Ambu® aScope™ Duodeno 2 Endoscopy System performed as expected and met the set test specifications.

Not Applicable

The Ambu® aScope™ Duodeno 2 Endoscopy System, consisting of Ambu® aScope™ Duodeno 2 and Ambu® aBox™2, has the same intended use and indications for use, and similar technological characteristics and principles of operation as the predicate devices.
The minor technological differences between the Ambu® aScope™ Duodeno 2 Endoscopy System and its predicate devices raise no new concerns regarding safety or effectiveness.
Thus, the Ambu® aScope™ Duodeno 2 Endoscopy System, consisting of Ambu® aScope™ Duodeno 2 and Ambu® aBox™2, is substantially equivalent to its predicate devices.