April 5, 2024

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

Re: K232919
Trade/Device Name: Ambu® aScope™ Gastro Large; Ambu® aBox™ 2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: March 5, 2024
Received: March 5, 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
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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 *(if known)*
K232919

Device Name
Ambu® aScope™ Gastro Large
Ambu® aBox™ 2

Indications for Use *(Describe)*
Ambu® aScope™ Gastro Large:

The endoscope is a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy.
The endoscope is intended to provide visualization via a compatible Ambu displaying unit and to be used with endotherapy accessories and other ancillary equipment.

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™ Gastro Large Endoscopy 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: Mette Andersen Job Title: Senior Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, 2750 Ballerup, Denmark Business Phone: +45 5381 3820 Email: meta@ambu.com	
Date Summary Prepared	September 19, 2023	
Device Trade Name	Ambu® aScope™ Gastro Large and Ambu® aBox™ 2	
Device Common Name	Endoscopy System	
Device Classification	21 CFR 876.1500 Gastroscope and Accessories, Flexible/rigid and Endoscopic Video Imaging System/Component, Gastroenterology-Urology Class II Product code: FDS, FET	
Legally Marketed Devices to which the Device is Substantially Equivalent	<u>Predicate Device for Ambu® aScope™ Gastro Large:</u> Ambu® aScope™ Gastro K212382	<u>Predicate Device for Ambu® aBox™ 2:</u> Ambu® aBox™ 2 K212382

Description of the Device	The Ambu® aScope™ Gastro Large Endoscopy System is a system used for endoscopic procedures in the upper gastrointestinal anatomy. It consists of a sterile, single-use, flexible endoscope, the Ambu® aScope™ Gastro Large, and a displaying unit, the Ambu® aBox™ 2.
Intended Use/Indications for Use	Ambu® aScope™ Gastro Large: The endoscope is a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy. The endoscope is intended to provide visualization via a compatible Ambu displaying unit and to be used with endotherapy accessories and other ancillary equipment. 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™ Gastro Large and its predicate device have the following same technological characteristics: • Both are sterile, single-use devices and are not intended to be reprocessed. • Both are flexible endoscopes with a maneuverable tip, a control section (handle) and an umbilical cord. • Both control the tip bending via two wheels at the handle and Bowden wires. • Both provide a working channel with the same working length. • Both have the same technological characteristics of the optical system. • Unlike the predicate device, the Ambu® aScope™ Gastro Large has a higher downwards bending angle and a larger working channel, outer diameter of the insertion tube, distal end and max. insertion portion. 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 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.

Performance Data – Bench

The following tests were performed to support the substantial equivalence of the Ambu® aScope™ Gastro Large Endoscopy System to the predicate device.

- Geometrical characteristics including
  - Dimensions of insertion portion (e.g., length, diameter)
  - Tip reach
  - Bending angles
- Functional performance including
  - Insufflation
  - Suction
  - Rinsing
  - Water Jet
- Optical performance comparison of
  - Field of view
  - Sharpness and Depth of field
  - Image intensity uniformity
  - Color performance
  - Noise characterization
  - Dynamic range
    Geometric distortion
- Photobiological safety
- Biocompatibility according to ISO 10993-1 including cytotoxicity, irritation, and sensitization
- Sterilization validation according to ISO 11135
- Transport validation
- Stability study
- Electrical Safety and performance according to IEC 60601-1 and IEC 60601-2-18
- Electromagnetic Compatibility according to IEC 60601-1-2

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

Conclusion

The Ambu® aScope™ Gastro Large Endoscopy System, consisting of Ambu® aScope™ Gastro Large and Ambu® aBox™ 2, has the same intended use and indications for use, and similar technological characteristics and principles of operation as the respective predicate devices.

The minor technological differences between the Ambu® aScope™ Gastro Large Endoscopy System and its predicate devices raise no new concerns regarding safety or effectiveness.

Thus, the devices constituting the Ambu® aScope™ Gastro Large Endoscopy System, Ambu® aScope™ Gastro Large and Ambu® aBox™ 2, are substantially equivalent to the respective predicate devices.