February 3, 2022

Ambu Inc.
Sanjay Parikh
Director, QA/RA
6230 Old Dobbin Lane, Suite 250
Columbia, MD 21045

Re: K212382
Trade/Device Name: Ambu® aScope™ Gastro, Ambu® aBox™2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: December 27, 2021
Received: January 4, 2022

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,

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)*
K212382

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

Indications for Use *(Describe)*

The aScope Gastro is a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy.
The aScope Gastro 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter	Ambu A/S Baltorpbakken 13 DK-2750 Ballerup Denmark Tel.: +45 7225 2000 Fax.: +45 7225 2050	
Contact Person	Name: Sanjay Parikh Job Title: Director, QA/RA Address: Ambu Inc. / 6230 Old Dobbin Lane, Suite 250 / 21045 Columbia / USA Business Phone: +1 443 367 4502 Email: sap@ambu.com	
Date Summary Prepared	July 29, 2021	
Device Trade Name	Ambu® aScope™ Gastro Ambu® aBox™ 2	
Device Common Name	Endoscopy System	
Device Classification	Ambu® aScope™ Gastro: Gastroscope And Accessories, Flexible/rigid Product Codes: FDS, FET 21 CFR 876.1500 Class II	Ambu® aBox™ 2: Endoscopic Video Imaging System/Component, Gastroenterology-Urology Product Codes: FET, FDS 21 CRF 876.1500 Class II
Legally Marketed devices to which the device is substantially equivalent	<u>Predicate Device:</u> OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 K100584	<u>Predicate Device:</u> OLYMPUS EXERA II Light Source (CLV-180) and Video System Center (CV-180) K100584
Description of the Device	The Ambu® Gastrointestinal (GI) Endoscopy System is a system used for endoscopic procedures in the gastrointestinal anatomy. It consists of a sterile, single-use, flexible endoscope, the Ambu® aScope™ Gastro, and a displaying unit, the Ambu® aBox™ 2.	

510(k) Application – Ambu® Gastrointestinal (GI) Endoscopy System

Indications for Use	The aScope Gastro is a sterile, single-use flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy. The aScope Gastro is intended to provide visualization via a compatible Ambu displaying unit and to be used with endo-therapy 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 and its predicate device have the following same technological characteristics: • Both are flexible endoscopes with 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 • Both have same technological characteristics as insertion portion length, working channel diameter, direction of view and bending angels • Unlike the predicate device, the Ambu® aScope™ Gastro is a sterile, single-use device and not intended to be reprocessed. 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 as brightness control, image contrast and sharpness adjustment and zoom function. • Contrary to the predicate device, the Ambu® aBox™ 2 is portable and has an integrated monitor, therefore, an external monitor is not necessary

Performance Data –Bench	The following tests to verify/validate the design and evaluate the performance of the Ambu® GI Endoscopy System were done.
	
	• Geometrical characteristics including
	  ○ Length of insertion tube, umbilical cord, tip
	  ○ Outer diameter of bending section, insertion tube and overlap of both
	  ○ Tip reach
	  ○ Bending angles
	• Functional performance including

	○ Insufflation ○ Suction ○ Rinsing ○ Water Jet • Optical performance including ○ Field of view ○ Direction of view ○ Sharpness and Depth of field ○ Geometric distortion ○ Image intensity uniformity ○ Color performance ○ Noise characterization ○ Dynamic range ○ Camera view orientation • Photobiological safety • Biocompatibility according ISO 10993-1 including cytotoxicity, irritation, and sensitization • Sterilization validation according ISO 11135 • Transport validation including packaging integrity • Stability study to document shelf life • Electrical Safety and performance according IEC 60601-1 and IEC 60601-2-18 • Electromagnetic Compatibility according IEC 60601-1-2 • Tests to confirm procedural performance In all instances, the Ambu® GI Endoscopy System performed as expected and met the set test specifications.
Conclusion	The Ambu® Gastrointestinal (GI) Endoscopy System, consisting of Ambu® aScope™Gastro 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® Gastrointestinal (GI) Endoscopy System and its predicate devices raise no new concerns regarding safety or effectiveness. Thus, the Ambu® Gastrointestinal (GI) Endoscopy System, consisting of Ambu® aScope™ Gastro and Ambu® aBox™ 2, is substantially equivalent to its predicate devices.