July 17, 2020

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

Re: K201098
Trade/Device Name: Ambu Duodeno System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT, FET
Dated: April 23, 2020
Received: April 24, 2020

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, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201098

Device Name
Ambu Duodeno System

Indications for Use *(Describe)*

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

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

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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Traditional 510(k) premarket notification Ambu Duodeno System	**Section 7** **510k Summary**	Ambu Ideas that work for life

Applicant Information

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Date Prepared: June 23rd, 2020

Identification of the proposed device

Device Name	Ambu Duodeno System
Components	Ambu aScope Duodeno Ambu aBox Duodeno
Common Name	Duodenoscope and Accessories
Classification	Endoscope and Accessories
Regulation	21 CFR 876.1500
Device Class	II
Product Code	FDT, FET
Review Panel	Gastroenterology/Urology

Predicate Devices

K143153	Olympus TJF-Q180V
K100584	EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180

Reference Devices

K173085	invendoscopy E210 System

Indication for Use/Intended Use

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

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

Device Description

The Ambu Duodeno System consists of a sterile single-use endoscope, the aScope Duodeno, and a processing unit, the aBox Duodeno.

The sterile single use duodenoscope aScope Duodeno consists of a flexible insertion tube with bendable tip, a control body and an umbilicus cord. The insertion tube has a bendable tip which is equipped with a camera to collect image data and a LED light source to illuminate the body cavity. The device contains a working channel through which additional instruments as biopsy devices may be introduced. The aScope Duodeno provides functions for lens washing, insufflation and suction.

The aBox Duodeno is an endoscopic video imaging system that receives video signals from the connected endoscope, controls the light at the endoscope tip and outputs this signal including a graphical user interface (GUI) to a connected external video monitor. It also provides signals to capture images by a connected external image capturing system. The aBox Duodeno also contains a peristaltic pump to provide water for the endoscope lens washing function. The peristaltic pump is controlled by the operator via the endoscope.

Comparison of Technological Characteristics with the Predicate Device

Both the aScope Duodeno and the Olympus TJF-Q180V consist of a flexible insertion tube with bendable tip, a control body and an umbilicus cord.

Both devices are equipped with working channel and an elevator.

Bending of the Tip and elevator of both devices, the aScope Duodeno and its predicate device, are controlled via bowden wires.

The aScope Duodeno and the Olympus TJF-Q180V share similar technological characteristics as working length, diameter, direction of view and bending angles.

Both devices are equipped with a HD camera whereby the field of view of the aScope Duodeno is bigger than the field of view of the Olympus TJF-Q180V.

Unlike the Olympus TJF-Q180V, the aScope Duodeno is a sterile, single-use device and not intended to be reprocessed.

Unlike the Olympus TJF-Q180V, the aScope Duodeno is equipped with LEDs for light illumination and does not need an additional light source.

Both the aBox Duodeno and the EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 (Olympus CV-180) are video processing systems. The aBox Duodeno and Olympus CV-180 share similar video output formats and are connectable to medical grade monitors.

Performance testing

Non-clinical testing was performed to validate the design and to evaluate substantial equivalency with the predicate device. This testing includes the following:

- Working length
- Insertion portion diameter
- Diameter working channel
- Bending angle endoscope tip
- Bending angle elevator
- Insufflation flow rate
- Direction of view
- Image resolution
- Depth of field
- Image distortion0
- Photobiological safety
- Signal to noise ratio
- Image illumination uniformity
- Color performance
- Rinsing flow rateSuction flow rate
- Instruments compatibility test
- System performance (functional performance)

The biocompatibility was evaluated in accordance with ISO 10993-1, including cytotoxicity; irritation and sensitization. The electrical safety of the system was tested according to IEC 60601-1 and IEC 60601-2-18. EMC was tested, in accordance with IEC 60601-1-2. The sterilization process was validated according to ISO 11135.

In all instances, the *Ambu Duodeno System* functioned as intended, performed as well as or better than the predicate and met individual test specifications.

Animal Testing

An animal study with two independent sessions was conducted to evaluate the clinical performance of the device.

The first session was performed in a bench top model utilizing a modified porcine upper GI tract with a simulated major duodenal papilla (MDP). The second session consisted of

in-vivo duodenoscopy with positioning for cannulation of the proximal duodena papilla (PDP) in a porcine model. In both sessions, the participants were asked to complete two separate runs, one using the Ambu Duodeno System and one using the predicate device.

For all test runs participants were asked to complete steps required for cannulation of the MDP/PDP using their standard technique. Both test sessions included evaluation of the following steps: intubation, navigation to the descending part of the duodenum, positioning for cannulation, tool insertion/retraction and withdrawal of duodenoscope. Furthermore, cannulation of the MDP was evaluated in the bench top test (first session), while procedure/device related tissue damage was recorded during the *in vivo* testing (second session). For all steps times from procedure start to step completed were recorded.

All participants were able to successfully complete all steps of both test sessions. The performance of the Ambu Duodeno System was comparable to that of the predicate device.

Substantial Equivalence

The *Ambu Duodeno System* 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 Duodeno System* and its predicate devices raise no new issues of safety or effectiveness.

Thus, the *Ambu Duodeno System* is substantially equivalent to its predicate devices.