April 2, 2020

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

Re: K193095
Trade/Device Name: Ambu aScope 4 Cysto
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: March 2, 2020
Received: March 4, 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,

Martha W. Betz, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K193095

Device Name
Ambu® aScope™ 4 Cysto

Indications for Use *(Describe)*
Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories.
Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment.
Ambu® aScope™ 4 Cysto is designed for use in adults.

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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Section 5 510(k) Summary

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the content and format of the 510(k) summery has been prepared in accordance with 21 CFR 807.92.

Submitter	Ambu A/S Baltorpbakken 13 DK-2750 Ballerup Denmark Tel.: +45 7225 2000 Fax.: +45 7225 2050
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Date Summary Prepared	April 1, 2020
Device Trade Name	Ambu® aScope™ 4 Cysto
Device Common Name	Flexible Cystoscope
Device Classification	Cystoscope and Accessories, Flexible/Rigid Product Codes: FAJ 21 CFR 876.1500 Class II
Legally Marketed devices to which the device is substantially equivalent	Predicate Device: Ambu® USR, Ambu® M, (K160766), Ambu A/S Reference Device: VISERA Cystovideoscope CYF-V2/VA2 (K133538), Olympus Medical Systems Corporation

Description of the Device

Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. Visualization will be achieved by Ambu® displaying unit. The Ambu® aScope™ 4 Cysto is intended to be used with a reusable Ambu® displaying unit to visualize the urethra and the bladder. The Ambu® aScope™ 4 Cysto can be operated by either the left or right hand. The optical module in the distal tip consists of a camera housing containing camera and LED light sources

Ambu® aScope™ 4 Cysto has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Working channel that can be used for graspers or other instrumentation
- Camera and LED light source at the distal tip
- Luer lock connector for irrigation and aspiration
- Sterilized by Ethylene Oxide sterilization
- For single use

Indications for Use

Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories.

Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment.

Ambu® aScope™ 4 Cysto is designed for use in adults.

Summary of the technological characteristics in comparison to the predicate device

Ambu® aScope™ 4 Cysto is similar to the predicate device in the following areas:

- It isa flexible endoscope with a manoeuvrable tip
- It has a handle with a control button giving the operator ability to manoeuvre the tip of the endoscope up and down
- It is a video endoscope with a camera located in the distal tip to provide an image on a separate monitor
- It´s provide illumination from the distal tip
- It is connected to a monitor by a cable
- It allows for irrigation
- It is single use and delivered sterile

Ambu® aScope™ 4 Cysto is different to the predicate devices in the following area:

- Ambu® aScope™ 4 Cysto has a working channel that can be used for graspers or other instrumentation. The predicate device has a working channel with an integrated grasper for stent removal
- The bending angle is larger in aScope 4 cysto than in the predicate, which is because the predicate has an integrated grasper

- Insertion cord working length is 390 mm for Ambu® aScope™ 4 Cysto while predicate device insertion cord working length is 380 mm.
- Distal end outer diameter is 5.4 mm for Ambu® aScope™ 4 Cysto while predicate device distal end outer diameter is 4.8 mm.
- Depth of field for Ambu® aScope™ 4 Cysto is 3-100 mm while for predicate device it is 3-50 mm.

Performance Data –Bench

The following data has been submitted in the premarket notification:

Declaration of conformity to the following recognized consensus standards applicable for Ambu® aScope™ 4 Cysto:

- ISO 8600-1, ISO 8600-3 and ISO 8600-4 Optics and optical instruments – Medical endoscopes and certain accessories.
- IEC 60601-2-18 ED 3.0:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Result: All tests were passed.

Performance test reports to document the following properties of the Ambu® aScope™ 4 Cysto:

- Insertion cord working length
- Insertion cord outer diameter
- Maximum diameter of the insertion portion
- Distal end outer diameter
- Maximum Diameter of the insertion portion
- Minimum diameter of the working channel
- Irrigation possible
- Luer Lock Connector to working channel
- Angulations range (Distal bending section)
- Field of view
- Depth of field
- Direction of View

Result: All tests were passed.

Sterilization
The sterilization method used is Ethylene Oxide (EO) with devices in a fixed chamber, in accordance with ISO 11135:2014.

Sterilization is conducted in a facility certified to EN ISO 13485:2016 with respect to sterilization in accordance with ISO 11135:2014.

Result: The Ambu® aScope™ 4 Cysto is sterile with a determination of lethal rate of the sterilization process to demonstrate achievement of the required SAL of 10^{-6} is in accordance to half cycle overkill approach as described in Annex B of ISO 11135:2014.

Shelf life
Performance test report to document shelf life. Tests were performed on finished, sterilized and aged products:

- Performance test
- Sterile Packaging Integrity

Result: All tests were passed.

	Biocompatibility tests reports to document that Ambu® aScope™ 4 Cysto complies with the requirements of ISO 10993-1. • Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous reactivity test (ISO 10993-10) Result: All tests were 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 were passed.
Performance Data – Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data, and comparison to predicate device it has been concluded that the functionality and intended use of Ambu® aScope™ 4 Cysto is equivalent to the predicate and reference devices. It is concluded that Ambu® aScope™ 4 Cysto is as safe and effective and performs as well as the chosen legally marketed predicate device.