October 16, 2024

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

Re: K240849
Trade/Device Name: Ambu® aScope™ 5 Cysto HD (Standard Deflection);
Ambu® aScope™ 5 Cysto HD (Reverse Deflection);
Ambu® aBox™ 2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, FET
Dated: March 27, 2024
Received: September 6, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240849

Device Name

Ambu® aScope™ 5 Cysto HD (Standard Deflection);
Ambu® aScope™ 5 Cysto HD (Reverse Deflection);
Ambu® aBox™ 2

Indications for Use *(Describe)*

aScope 5 Cysto HD is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via a compatible Ambu displaying unit and can be used with endoscopic accessories and instruments.

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) #: K240849

510(k) Summary

Prepared on: 2024-09-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ambu A/S
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Correspondent Contact	Mr. Sanjay Parikh
Correspondent Contact Email	sap@ambu.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ambu® aScope™ 5 Cysto HD (Standard Deflection); Ambu® aScope™ 5 Cysto HD (Reverse Deflection); Ambu® aBox™ 2
Common Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ, FET (CLASS 2) - ENDOSCOPIC VIDEO IMAGING SYSTEM/COMP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193095	Ambu® aScope™ 4 Cysto	FAJ
K230332	Ambu® aBox™ 2	FET

Device Description Summary

21 CFR 807.92(a)(4)

The Ambu® aScope™ 5 Cysto HD System is a combination of an endoscope, Ambu® aScope™ 5 Cysto HD, and a compatible displaying unit, Ambu® aBox™ 2.

Ambu aScope 5 Cysto HD is a sterile single-use and flexible endoscope for use within the lower urinary tract. The cystoscope is intended to be used with a compatible and reusable Ambu displaying unit to visualise the urethra and the bladder.

The cystoscope is powered by connecting to the displaying unit. Ambu® aScope 5 Cysto HD can be used with endoscopic instruments and accessories, instillation of fluids (e.g. saline for expanding the bladder) and suctioning of fluids. Ambu® aScope 5 Cysto HD shall be disposed of as infected medical device with electronic components.

Ambu® aScope 5 Cysto HD is available in one size and can be operated by either the left or right hand. Two variants of the cystoscope are available: aScope 5 Cysto HD – Reverse Deflection and aScope 5 Cysto HD – Standard Deflection. Apart from the mode of deflection, the cystoscopes share the same design.

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™ 5 Cysto HD to a monitor
- Can record, store and transport image data from Ambu® aScope™ 5 Cysto HD
- 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)

aScope 5 Cysto HD is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via a compatible Ambu displaying unit and can be used with endoscopic accessories and instruments.

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™ 5 Cysto HD has the same intended use as the predicate device.
The Ambu® aBox™ 2 has the same intended use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Ambu® aScope™ 5 Cysto HD and its predicate device have the following same technological charateristics:
- Both devices control the maneuverable distal end by moving the control button at the handle.
- Both devices have a working channel with one inlet and outlet.
- Both devices have a camera at distal tip of insertion cord and use LED light source to illuminate.
- Both devices are designed to connect to a compatible monitor.
- Both devices are sterilized by Ethylene Oxide.

Ambu® aScope™ 5 Cysto HD differs from its predicate device in some technical specifications, including insertion portion and camera chip type. The differences do not introduce issues for safety and performance.
Ambu® aScope™ 5 Cysto HD has passed the performance testing. Ambu® aScope™ 5 Cysto HD is substantially equivalent to the predicate device in terms of safety and performance.

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 were performed to verify/validate the design and evaluate the performance of the Ambu® aScope™ 5 Cysto HD System:

Verification tests including:
- Bending performance
- Irrigation performance
- Working channel performance

• Laser Fiber Activation Compatibility performance
• High Frequency Tool Activation Compatibility performance
• Functionality

Optical performance tests including:
• Field of view (ISO 8600-3)
• Direction of view (ISO 8600-3)
• Sharpness and Depth of field
• Image intensity uniformity
• Geometric distortion
• Resolution
• Color performance
• Noise performance
• Dynamic range

Photobiological safety according to IEC 62471
Transportation study according to ASTM D4169
Sterilization validation according to ISO 11135
Stability study to document shelf life according to ASTM F1980
Sterile packaging integrity

Biocompatibility according to ISO 10993-1 including tests for:
• Physical and/or chemical information
• Cytotoxicity
• Irritation
• Sensitization

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™ 5 Cysto HD System performed as expected and met the test specifications set.

N/A

All included bench tests, which have been designed to evaluate substantial equivalence as well as the product's conformity to established quality and performance measures, have been successfully conducted, documented, and have passed the predefined acceptance criteria.
As a result, it is concluded that the devices constituting the Ambu® aScope™ 5 Cysto HD System meet their predefined specifications, perform as intended and are equivalent to the predicate devices listed in the Predicates and Substantial Equivalence section.