June 24, 2024

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

Re: K233630
Trade/Device Name: Ambu® aScope™ 5 Uretero (Standard Deflection);
Ambu® aScope™ 5 Uretero (Reverse Deflection);
Ambu® aBox™ 2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: November 13, 2023
Received: May 28, 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,

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)*

K233630

Device Name

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

Indications for Use *(Describe)*

The aScope 5 Uretero is a sterile, single-use, flexible, digital video ureteroscope intended to be used for endoscopic access and visual guidance in the upper urinary tract.
aScope 5 Uretero is intended to be used with the compatible Ambu displaying unit and can be used in conjunction with endoscopic instruments via its working channel.
aScope 5 Uretero is intended for patients requiring retrograde (transurethral) and/or antegrade (percutaneous) ureteroscopy procedures for visualization and examination with a flexible ureteroscope, and for removal of renal and ureter calculi.

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) #: K233630

# 510(k) Summary

Prepared on: 2024-05-26

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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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 Uretero (Standard Deflection);<br>Ambu® aScope™ 5 Uretero (Reverse Deflection);<br>Ambu® aBox™ 2 |
| Common Name | Endoscope and accessories |
| Classification Name | Ureteroscope And Accessories, Flexible/Rigid |
| Regulation Number | 876.1500 |
| Product Code | FGB |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K153049 | LithoVue Single-Use Digital Flexible Ureteroscope | FGB |
| K230332 | Ambu® aBox™ 2 | FET |

## Device Description Summary

21 CFR 807.92(a)(4)

The Ambu® aScope™ 5 Ureteroscopy System is a combination of an endoscope, Ambu® aScope™ 5 Uretero and a displaying unit, the Ambu® aBox™ 2.

The Ambu® aScope™ 5 Uretero is a sterile, single-use, flexible, digital video ureteroscope. The Ambu® aScope™ 5 Uretero can be used in retrograde (transurethral) and/or antegrade (percutaneous) ureteroscopy procedures for providing endoscopic access and visual

guidance to and in the upper urinary tract.

The Ambu® aScope™ 5 Uretero is available in one size and can be operated by either left or right hand. The Ambu® aScope™ 5 Uretero can be used with endoscopic accessories. The working channel system allows the passage of endoscopic instruments, instillation/ suction of fluids. The aScope 5 Uretero is intended to be used with a compatible Ambu displaying unit - Ambu® aBox™ 2.

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

The aScope 5 Uretero is a sterile, single-use, flexible, digital video ureteroscope intended to be used for endoscopic access and visual guidance in the upper urinary tract.
aScope 5 Uretero is intended to be used with the compatible Ambu displaying unit and can be used in conjunction with endoscopic instruments via its working channel.
aScope 5 Uretero is intended for patients requiring retrograde (transurethral) and/or antegrade (percutaneous) ureteroscopy procedures for visualization and examination with a flexible ureteroscope, and for removal of renal and ureter calculi.

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)

Ambu® aScope™ 5 Uretero has the same indications for use as the predicate device.
Ambu® aBox™ 2 has the same indications for use as the predicate device.

## Technological Comparison

21 CFR 807.92(a)(6)

Ambu® aScope™ 5 Uretero and its predicate device have the following same technological characteristics:
- Both devices control the maneuverable distal end by moving the control button at the handle.
- Both devices have a working channel with two inlets.
- 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 Uretero differs from its predicate device in some technical specifications, including insertion portion and field of view. The differences do not introduce issues for safety and performance. Ambu® aScope™ 5 Uretero has passed the performance testing.

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 Uretero System:

Verification tests including:
- Insertion portion dimensions and performance
- Working channel performance
- Bending performance
- Irrigation performance
- Suction 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 has been assessed according to:
• Physical and/or chemical information addressed according to ISO 10993-1
• Cytotoxicity tested according to ISO 10993-5
• Irritation tested according to ISO 10993-23
• Sensitization tested according to ISO 10993-10
• Material-mediated pyrogenicity tested according to ISO 10993-11
• Acute Systemic Toxicity tested according to ISO 10993-11

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 Uretero 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 Ureteroscopy System meet their predefined specifications, perform as intended and are equivalent to the predicate devices listed in the Predicates and Substantial Equivalence section.