August 16, 2024

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

Re: K242108
Trade/Device Name: Ambu® aScope™ 5 Uretero (Standard Deflection); Ambu® aScope™ 5 Uretero (Reverse Deflection); Ambu® aView™ 2 Advance
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FGB, FET
Dated: July 3, 2024
Received: July 18, 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,

Sharon M. Andrews -S

Sharon M. Andrews
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)*

K242108

Device Name

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

Indications for Use *(Describe)*

Ambu® 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. Ambu® 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. Ambu® 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.

Ambu® aView™ 2 Advance 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.

510(k) Summary

Prepared on: 2024-08-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ambu A/S
Applicant Address	Baltorpbakken 13 Ballerup 2750 Denmark
Applicant Contact Telephone	+4572252679
Applicant Contact	Ms. Gamze Yilan
Applicant Contact Email	gayi@ambu.com
Correspondent Name	Ambu Inc.
Correspondent Address	6721 Columbia Gateway Drive, Suite 200 Columbia MD 21046 United States
Correspondent Contact Telephone	+1 443 367 4502
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); Ambu® aScope™ 5 Uretero (Reverse Deflection); Ambu® aView™ 2 Advance
Common Name	Ureteroscope and Accessories
Classification Name	Endoscope and Accessories
Regulation Number	876.1500
Product Code(s)	FGB, 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
K233630	Ambu® aScope™ 5 Uretero	FGB
K233671	Ambu® aView™ 2 Advance	EOQ

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® aView™ 2 Advance.

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 Ambu® aScope™ 5 Uretero is intended to be used with a compatible Ambu displaying unit, Ambu® aView™ 2 Advance.

The Ambu® aView™ 2 Advance, 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 12.8" LCD screen. The displaying unit is powered by a rechargeable lithium-ion battery and includes a power supply with region-specific power cable.

The Ambu® aView™ 2 Advance 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

The predicate device Ambu® aScope™ 5 Uretero (K233630) has not been subject to a design related recall. The predicate device Ambu® aView™ 2 Advance (K233671) has been subject to a design related recall, which was resolved via a labeling update.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Ambu® 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. Ambu® 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. Ambu® 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.

Ambu® aView™ 2 Advance 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 intended use as its predicate device (Ambu® aScope™ 5 Uretero cleared in K233630).
Ambu® aView™ 2 Advance has the same intended use as the predicate device (Ambu® aView™ 2 Advance cleared in K233671).

Technological Comparison

21 CFR 807.92(a)(6)

Ambu® aScope™ 5 Uretero has similar technological characteristics as its predicate device. The only difference is that the applicant device is compatible with Ambu® aView™ 2 Advance in addition to Ambu® aBox™ 2. The additional compatibility to Ambu® aView™ 2 Advance does not affect the safety or effectiveness of the Ambu® aScope™ 5 Uretero.

Ambu® aView™ 2 Advance 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.

In conclusion, the different technological characteristics of the subject device and predicate device do not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

In addition to the performance testing described in the original 510(k)s (K233630 and K233671), additional testing has been performed to address the risks associated with the additional compatibility and to support substantial equivalence to the predicate devices:

• Optical performance tests:
  o Field of view and Direction of view
  o Sharpness and Depth of field
  o Image intensity uniformity
  o Geometric distortion
  o Resolution

- o Color performance
- o Noise performance
- o Dynamic range

• Software verification testing
• Electrical Safety according to IEC 60601-1:2005+A1:2012+A2:2020 Ed. 3.2 and IEC 60601-2-18:2009 Ed. 3.0
• Electromagnetic Compatibility according to IEC 60601-1-2:2014+A1:2020 Ed. 4.1

Overall, the Ambu® aScope™ 5 Ureteroscopy System performed as expected and met the test specifications set.

In conclusion, Ambu® aScope™ 5 Uretero and Ambu® aView™ 2 Advance constituting the Ambu® aScope™ 5 Ureteroscopy System, have the same intended use/indications for use and similar technological characteristics as the predicate devices.

The minor technological differences between Ambu® aScope™ 5 Uretero and Ambu® aView™ 2 Advance and their respective predicate device do not raise any different questions regarding safety or effectiveness and have been addressed in the performance testing listed above.

Therefore, it is concluded that the devices in the subject Ambu® aScope™ 5 Ureteroscopy System is substantially equivalent to the legally marketed predicates.