June 11, 2025

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

Re: K250269
Trade/Device Name: Ambu® aScope™ 5 Cysto HD (Standard Deflection);
Ambu® aScope™ 5 Cysto HD (Reverse Deflection)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Received: May 16, 2025

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 J. Antonino -S

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)*

K250269

Device Name

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

Indications for Use *(Describe)*

aScope 5 Cysto HD is a sterile, single-use, flexible cysto-nephroscope intended to be used for endoscopic access to and examination of the lower urinary tract and kidney.

The cysto-nephroscope is intended to provide visualization via a compatible Ambu displaying unit and can be used with endoscopic accessories and instruments.

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) #: K250269

510(k) Summary

Prepared on: 2025-05-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ambu A/S
Applicant Address	Baltorpbakken 13 Ballerup 2750 Denmark
Applicant Contact Telephone	+4982332189113
Applicant Contact	Ms. Martina Krautwald
Applicant Contact Email	maka@ambu.com
Correspondent Name	Ambu Inc.
Correspondent Address	6721 Columbia Gateway Drive, Suite 200 Columbia MD 21046 United States
Correspondent Contact Telephone	+1 443 831 9844
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)
Common Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221683	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYP	FAJ

Device Description Summary

21 CFR 807.92(a)(4)

The Ambu® aScope™ 5 Cysto HD is a sterile single-use and flexible endoscope for use within the lower urinary tract and kidney via antegrade (percutaneous) access. The cysto-nephroscope is intended to be used with a compatible and reusable Ambu displaying unit (the Ambu® aBox™ 2 or the Ambu® aView™ 2 Advance) to visualise the urethra and the bladder as well as the kidney.

The cysto-nephroscope is powered by connecting to the displaying unit. Ambu® aScope 5 Cysto HD can be used with endoscopic instruments and accessories, for 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 cysto-nephroscope are available: aScope 5 Cysto HD – Reverse Deflection and aScope 5 Cysto HD – Standard Deflection. Apart from the mode of deflection, the cysto-nephroscopes share the same design.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

aScope 5 Cysto HD is a sterile, single-use, flexible cysto-nephroscope intended to be used for endoscopic access to and examination of the lower urinary tract and kidney.

The cysto-nephroscope is intended to provide visualization via a compatible Ambu displaying unit and can be used with endoscopic accessories and instruments.

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.

Technological Comparison 21 CFR 807.92(a)(6)

Ambu® aScope™ 5 Cysto HD 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 one inlet and outlet.
- Both devices have a camera at the distal tip of the insertion cord.
- Both devices are designed to connect to a compatible monitor.

Ambu® aScope™ 5 Cysto HD differs from its predicate device in some technical specifications, including the insertion portion diameter. Furthermore, the Ambu® aScope™ 5 Cysto HD is a single-use device whereas the predicate device is reusable. 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.

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.

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
• Material-mediated pyrogenicity
• Acute Systemic Toxicity

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 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 Ambu® aScope™ 5 Cysto HD meets the predefined specifications, performs as intended and is equivalent to the predicate device listed in the Predicates and Substantial Equivalence section.