



Food and Drug Administration
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August 17, 2016

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

Re: K160766
Trade/Device Name: Ambu® USR, Ambu® M
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, OCZ
Dated: July 11, 2016
Received: July 12, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160766

Device Name

Ambu® USR

Ambu® M

Ambu® USR is a sterile, single use flexible cystoscope designed for removal of double loop ureteral stents accessible in the bladder via a urethral insertion in adults.

Ambu® USR has been designed to be used with the reusable Ambu® M to visualize the observations obtained by Ambu® USR.

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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510(k) Application –Ambu® USR and Ambu® M

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) summary has been prepared in accordance with 21 CFR 807.92.

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Date Summary Prepared	August 17, 2016			
Device Trade Name	Ambu® USR Ambu® M			
Device Common Name	Flexible Cystoscope			
Device Classification	Cystoscope and Accessories, Flexible/Rigid Product Codes: FAJ Endoscopic grasping/cutting instrument, non-powered Product Codes: OCZ 21 CFR 876.1500 Class II			
Legally Marketed devices to which the device is substantially equivalent		<u>Manufacturer</u>	<u>Trade Name</u>	<u>510k number</u>
	A:	Olympus Corporation	VISERA Cystovideoscope CYF-V/VA and CYF-V2/VA2	K021074 and K133538
	B:	Vision Sciences	CST-5000 Flexible Video Cystoscope	K072180
	C+E:	Ambu A/S	Ambu® aScope 3™ 5.0/2.2 and Ambu® aView	K130845

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D:	Olympus Corporation	Olympus FG-4L-1 Grasping Forceps	K955066
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Description of the Device

The system consists of Ambu® USR and Ambu® M Monitor. Ambu® USR is a single use flexible cystoscope with an integrated grasper designed for removal of double loop ureteral stents accessible in the bladder via a urethral insertion. Ambu® USR is connected to the reusable Ambu® M Monitor that displays the video image from Ambu® USR.

Ambu® USR has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Integrated grasper controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Luer lock connector for irrigation and aspiration
- Sterilized by Ethylene Oxide sterilization
- For single use

Ambu® M Monitor has the following physical and performance characteristics:

- Displays the image from Ambu® USR on the screen.
- Records snapshots or video of image from Ambu® USR.

Indications for Use

Ambu® USR is a sterile, single use flexible cystoscope designed for removal of double loop ureteral stents accessible in the bladder via a urethral insertion in adults.

Ambu® USR has been designed to be used with the reusable Ambu® M to visualize the observations obtained by Ambu® USR.

Summary of the technological characteristics in comparison to the predicate devices

Ambu® USR is similar to the predicate devices in the following areas:

- They are all flexible endoscopes with a maneuverable tip
- They all have a handle with a control button giving the operator ability to steer the tip of the scope up and down
- They are all video scopes with a camera located in the distal tip to provide an image on a separate monitor
- They all provide illumination from the distal tip
- They are all connected to a monitor by a cable
- Ambu® USR has an integrated grasper. Predicate A, B and C have a working channel that can be used for graspers or other instrumentation.
- Grasper in Ambu® USR and Predicate D are rat tooth designs with two jaws in a V-shape and teeth at the end.

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**Performance
Data –Bench**

- Grasper in Ambu® USR and Predicate D are made of stainless steel components
- They all allow for irrigation

Ambu® M Monitor is similar to Predicate E in the following areas:

- Both display a live image on a TFT-screen
- Both supply power to the endoscope via a connection to the monitor
- Both are powered by a rechargeable battery or by a power supply
- Both systems are operated either on battery or standard wall outlet
- Both monitors are portable

The following data has been submitted in the premarket notification:

Declaration of conformity to the following recognized consensus standards applicable for Ambu® USR:

- ISO 8600-1, ISO 8600-3 and ISO 8600-4 Optics and optical instruments – Medical endoscopes and certain accessories.
- ISO 594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.

Result: All tests were passed.

Performance test reports to document the following properties of the Ambu® USR:

- Length and diameters of insertion cord
- Bending angle and durability of bending section
- Image quality during 1 hour operation
- Irrigation system functionality
- Grasper functionality and image quality
- Grasper stent pull force

Result: All tests were passed.

Performance test report to document shelf life of Ambu® USR. Tests were performed on finished, sterilized, shipped and aged products:

- Performance test of Ambu® USR
- Sterile Packaging Integrity

Result: All tests were passed.

Biocompatibility tests reports to document that Ambu® USR 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.

Performance test report to document the following properties of the Ambu® M monitor (reusable):

- Cleaning and Low Level Disinfection validation

Result: The test was 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.

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	Result: All tests were passed.
Performance Data – Clinical	Not applicable.
Conclusion	<p>Based on the indication for use, technological characteristics, performance data and comparison to predicate devices it has been concluded that the functionality and intended use of Ambu® USR and Ambu® M is equivalent to the predicate devices.</p> <p>It is concluded that Ambu® USR and Ambu® M are as safe and as effective and perform as well as or better than the chosen legally marketed predicate devices.</p>