K093186

APR 1 3 2010

Section 7 – 510(k) Summary

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the 510(k) has been prepared in accordance with 21 CFR 807.92

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Date Summary Prepared	September 30, 2009
Device Trade Name	Ambu® aScope™ Ambu® aScope™ Monitor
Device Common Name	Endoscope for endotracheal intubation
Device Classification	Tracheal Tube Product Code: BTR 21 CFR 868.5730 Class II

Legally Marketed devices to which the device is substantially equivalent

Manufacturer	Trade Name	510k number
Olympus	Olympus Bronchoscope BF-160	K023984
Olympus	Olympus LF-1 Tracheal intubation fiberscope	K850978
ETView Ltd	Traceoscopic Ventilation Tube System	K052233
EZC	EZC Medical, LLC, IntubaidFlex	K090777

Description of the Device	Ambu aScope System consist of Ambu aScope and Ambu aScope Monitor. Ambu aScope is for placement of an endotracheal tube (ETT), an ETT size 6 or larger can be used. A camera at the distal tip of the aScope provides the user with an indication of the placement of the aScope. The manoeuvrable tip allows the user to guide the ETT in the desired direction. Ambu aScope is for single patient use and it is sterile. The Ambu aScope must be connected to Ambu aScope Monitor. The monitor displays the image and it is reusable. <u>Ambu aScope has the following physical and performance characteristics:</u> - Manoeuvrable tip controlled by the clinician - Flexible insertion cord - Camera and LED light source at the distal tip - Topical Anaesthetics can be administered to the patient via a channel, with standard luer connector - Sterile by Ethylene Oxide sterilisation - For Single Patient Use <u>Ambu aScope Monitor has the following physical and performance characteristics:</u> - Displays the image from Ambu aScope on the screen. - Can be fixed to e.g. an IV pole. - By connecting a Video Out Cable to the Ambu aScope Monitor the image can be displayed and/or recorded on an external monitor and/or video recorder. - Reusable device.
Intended use	The Ambu aScope is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non-difficult and difficult intubation procedures. The Ambu aScope achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu aScope is in the human anatomy. The flexible tip of the Ambu aScope allows the user to guide the ETT in the desired direction. The system is for use in a hospital environment. The target population is adults/children that have been clinically evaluated for ETT size 6 or larger. Topical anesthetics can be administered via a channel with a luer connector.

Summary of the technological characteristics in comparison to the predicate devices

Ambu aScope is similar to EZC Medical LCC, Intubaid Flex (K090777) in the following areas:

- They possess a similar Indication for Use.
- None of the devices possess a suction port.
- They both are flexible scopes with a manoeuvrable tip.
- They are single-use devices, which are delivered sterile.
- They both use a LED-light source located at the tip of the scopes
- They possess a CMOS camera located at the distal tip to provide an image
- They have a handle with a control button giving the operator the ability to steer the tip of the scope up and down
- In both devices, an image is provided on a separate monitor

Ambu aScope is similar to ETView, Tracheoscopic Ventilation Tube (TVT) System (K052233) in the following areas:

- It uses LED as light source located at the tip of the scopes
- A CMOS camera at the distal tip to provide an image
- It is a single use device, which is delivered sterile.
- None of the devices possess a suction port.

They are different in design in that TVT is an Endotracheal Tube by it self, Ambu aScope is an aid in the placement of the ETT. As well TVT does not have manoeuvrable tip as the Ambu aScope.

Ambu aScope system is similar to Olympus Bronchoscope, BF-160 (K023984) and Olympus LF-1 Tracheal intubation fiberscope (K850978) in that it consist of:

- A handle with a control button giving the operator the ability to steer the tip of the scope up and down
- It is possible to apply topical anesthesia at the tip of the insertion cord
- Light source at the tip
- An image is provided at a monitor
- Used for tracheal intubation for insertion and navigation into the trachea and easier placement of endotracheal tubes

The Ambu aScope System is based on the same basic principles and design and will fit in on all the characteristics, except that it is using LED as a light source and a CMOS camera at the distal tip to provide images. Moreover Ambu aScope is a single use device.

Ambu concludes that the Ambu aScope and Ambu aScope Monitor is substantially equivalent to the predicate devices.

Performance Data - Bench

The following data has been submitted in the premarket notification:

Ambu has provided declaration of conformity to the following recognized consensus standards applicable for this type of device:
- 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.

The declaration of conformity is based on test data.
Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aScope (single use):
- Manoeuvrability of tip (accept criteria: min 120 ° to each side)
- Endurance of the bending section (accept criteria: 50 bends to each side of minimum 90° and 10 bends to each side of minimum 120°)
- Channel for topical anaesthetics (accept criteria: verification of ability to administer topical anaesthetics through the channel – when 1 ml is injected at least 0.8 ml was expelled in the distal end)
- Temperature at distal end of Ambu aScope (accept criteria: temperature below 41 °C)

Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aScope Monitor (reusable):
- Imaging performance; evaluation of colours, flickering, contrast and brightness, rated on a scale from 1-3, where 1 is best. (accept criteria: rating 1 and max 2 ratings of 2, when 32 scopes are evaluated for all 4 properties (128 evaluations))
- Cleaning endurance of aScope Monitor (accept criteria: monitor can withstand the prescribed cleaning and disinfection method for 150 times reprocessing)
- Battery capacity of Ambu aScope Monitor (accept criteria: at least 70% battery capacity after 150 times charging and de-charging)

Result: All tests were passed.

Performance test report was submitted to document Shelf life of Ambu aScope. Testing was done on finished, sterilized, shipped and aged products:
- Performance test of the aScope. Test according to Final Quality Inspection Procedure of Ambu aScope.
  Accept criteria: Product specifications fulfilled
- Sterile packaging integrity of the aScope pouch.
  Accept criteria: The seal strength must be greater than 0.4 N when tested according to ASTM F88.

Result: All tests were passed

Since the device is in compliance with the listed standards and have passed the listed performance tests, it is concluded that technological characteristics of Ambu aScope and Ambu aScope Monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.

Environmental tests to demonstrate the compliance to the following standards:
Transportation in designated packaging:

- EN 60068-2-27 Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock: 500 repetitive shocks (bump) in each of 6 directions 400 m/s2 (40g)
- EN 60068-2-64 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance: Random vibration 1.6 grms, 10-150Hz, 30 min/axis
- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens: 12 falls from 1.2m height

Tests performed with the product without its packaging:
Bounce

- EN 60608-2-6 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal): Sinus vibration 5Hz, 1grms, 1 hour.

Free fall

- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens:
  aScope: 2 falls per relevant orientation from 1.2m height to a smooth concrete surface.
  aScope Monitor: 2 falls per relevant orientation from 0.2m height to a smooth concrete surface.

After each of the above environmental tests, the packaging integrity and the device were inspected, and performance test of the device was performed.
Result: All products and packaging passed the tests.

Based on the above environmental testing Ambu has concluded that Ambu aScope and Ambu aScope Monitor, can withstand the stresses applied to the product during transport and handling prior to the use of the device, and is as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.

	Data for compliance to the general requirements for the device were submitted: Biocompatibility tests shows that the device complies with the requirements of ISO 10993-1: - Cytotoxicity (ISO 10993-5) - S ensitization (ISO 10993-10) - Intracutaneous reactivity test (ISO 10993-10) Result: All tests were passed. Tests that verifies the following properties: - Cleaning validation and Liquid Chemical Sterilization and Disinfection Validation of the Ambu aScope Monitor according to AAMI TIR12 and AAMI TIR30, to validate the prescribed method of cleaning and disinfection. - Electro Magnetic Compatibility in compliance with IEC 60601-1-2. - Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18. Result: All tests were passed. Since the device passed all the tests to demonstrate compliance to the general requirements for this kind of device, it is concluded that Ambu aScope and Ambu aScope monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.
Performance Data - Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate devices it has been concluded that the Ambu aScope and Ambu aScope Monitor has equivalent functionality and intended use as the predicate devices. It is concluded that Ambu aScope and Ambu aScope Monitor are as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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APR 1 3 2010

Ambu A/S
C/O Mr. Sanjay Parikh
Vice President Operations
Ambu, Incorporated
6740 Baymeadow Drive
Glen Burnie, Maryland 21060

Re: K093186
Trade/Device Name: Ambu® aScope™ and Ambu® aScope™ Monitor
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: April 09, 2010
Received: April 12, 2010

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093186

Device Name: Ambu® aScope™ and Ambu® aScope™ Monitor

Indications For Use:

The Ambu aScope is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non difficult and difficult intubation procedures. The Ambu aScope achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu aScope is in the human anatomy. The flexible tip of the Ambu aScope allows the user to guide the ETT in the desired direction.

The system is for use in a hospital environment. The target population is adults/children that have been clinically evaluated for ETT size 6 or larger.

Topical anesthetics can be administered via a channel with a luer connector

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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