K102824
JAN 28 2011

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

Submitter

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Date Summary Prepared

September 21, 2010

Device Trade Name

Ambu® Oval Silicone Resuscitator, Adult
Ambu® Oval Silicone Resuscitator, Pediatric

Device Common Name

Manual Resuscitator (Reusable)

Device Classification

Ventilator, Emergency, Manual
Product Codes: BTM
21 CFR 868.5915
Class II

Legally Marketed devices to which the device is substantially equivalent:

Ambu Oval Resuscitator, Adult

Manufacturer	Trade Name	510(k) number
Ambu Silicone	Resuscitator, Adult	K910040
Ambu	Mark IV Resuscitator, Adult	K053140

Ambu Oval Resuscitator, Pediatric

Manufacturer	Trade Name	510(k) number
Ambu Silicone	Resuscitator, Infant/Child	K914187
Ambu	Mark IV Resuscitator, Baby	K053142

Description of the Device

Ambu Oval Resuscitators is for manual pulmonary resuscitation and emergency respiratory support. Ambu Oval Resuscitators are in two sizes; Adult & Pediatric. It is a reusable product.

The product consists of a resuscitator bag, inlet valve and outlet valve. Oxygen reservoirs can be mounted to the inlet valve.

Facemask, Endotracheal Tube or similar device is connected to the resuscitator patient valve to ensure contact to the patient's airway.

The inlet valve allows ambient air with or without supplementary oxygen to flow into the bag and prevents air flowing backwards from the bag through the inlet valve during ventilation.

When the resuscitator bag is compressed air is delivered via the patient valve to the patient. The bag is made of a self-expanding material, which ensures the bag to have sufficient compression and recoiling properties.

Pressure limiting valve (40 cmH_2O) with an override mechanism is placed in patient valve housing. On Pediatric resuscitators there are always a Pressure limiting valve and on Adult resuscitators there are product types available with and without Pressure limiting valve.
Ambu Oval Resuscitator complies with ISO 10651-4: Particular requirements for operator powered resuscitators.

Ambu Oval Resuscitators have the following physical and performance characteristics:

- Provided in two sizes; Adult & Pediatric
- Reusable
- 22 mm (outside) / 15 mm (inside) Patient Connector
- 30 mm Expiratory Connector
- Resuscitator Volume: Pediatric: 635 ml - Adult: 1475 ml
- Stoke Volume one hand: Pediatric: 450 ml - Adult: 700 ml
- Stroke Volume two hands: Pediatric: NA - Adult: 1475 ml
- Can be used with ambient air and/or supplementary oxygen.
- Pressure Limiting Valve: 40 cmH_2O / 4.0 kPa, and port for attachment of manometer

Intended use

Ambu Oval Resuscitator Adult and Pediatric:
Ambu® Oval Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support. For use by CPR-trained personnel only, in hospital and pre-hospital settings.
The Ambu® Oval Resuscitator is a reusable. The range of application for the sizes are:
Adult: Adults and children with a body weight of more than approx. 30 kg (66 lbs.)
Pediatric: Infants and children with a body weight between approx. 10-30 kg (22-66 lbs).

Summary of the technological characteristics in comparison to the predicate devices

Ambu Oval Resuscitators, Adult is substantially equivalent to:

- Ambu Silicone Resuscitator, Adult (K910040)
- Ambu Mark IV Resuscitator, Adult (K053140)

The operation and technological characteristics of Ambu Oval Resuscitator, Adult is the same as the predicate devices operation and technological characteristics; The only difference is that Ambu Mark IV Resuscitator is a double wall design, while Oval Resuscitator is single wall design.
All devices have the same intended use.
Ambu concludes that the Ambu Oval Resuscitators, Adult is substantially equivalent to the predicate devices.

Ambu Oval Resuscitators, Pediatric is substantially equivalent to:

- Ambu Silicone Resuscitator, Infant/Child (K914187)
- Ambu Mark IV Resuscitator, Baby (K053142)

The operation and technological characteristics of Ambu Oval Resuscitator, Pediatric is the same as the predicate devices operation and technological characteristics; The only difference is that Ambu Mark IV Resuscitator is a double wall design, while Oval Resuscitator is single wall design.
All devices have the same intended use.
Ambu concludes that the Ambu Oval Resuscitators, Pediatric 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 ISO 10651-4 and ISO 5356-1
- Test reports for Biocompatibility shows that the devices complies with the requirements of ISO 10993-1:
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Intracutaneous reactivity test (ISO 10993-10)
- Data to demonstrate Automated Cleaning Validation and Steam Sterilization Validation According to AAMI TIR 12 and AAMI TIR 30

Bench testing was performed and the results of such bench testing demonstrate that the device is as safe and effective as the currently marketed predicate devices.

Performance Data – Clinical:

No clinical tests are performed

Conclusion:

Based on the indication for use, operation and technological characteristics, and performance testing it has been concluded that the Ambu Oval Resuscitator, Adult and Pediatric have equivalent functionality and intended use as the predicate devices.
It is concluded that Ambu Oval Resuscitator, Adult and Pediatric are as safe and effective and performs as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

JAN 28 2011

Re: K102824
Trade/Device Name: Ambu Oval Silicone Resuscitator, Adult and Pediatric
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: January 12, 2011
Received: January 13, 2011

Dear Mr. 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, B.S., M.S., M.B.A.
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): Not known

Device Name: Ambu Oval Silicone Resuscitator, Adult and Pediatric

Indications For Use:

The Ambu® Oval Silicone resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support.For use by CPR-trained personnel only, in hospital and pre-hospital settings.
The Ambu Oval Silicone resuscitator is reusable. The range of application for the sizes are:

Adult: Adults and children with a body weight of more than approx. 30 kg (66 lbs.).
Paediatric: Infants and children with a body weight between approx. 10~30 kg (22~66 lbs.)

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

510(k) Number: K102824