DEC 2 3 2005

K053140

510(k) Summary

1. 510(k) owner:

Ambu A/S
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Denmark
Tel.: +45 72252000
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Contact person:
Laila Strange Lundtoft
Regulatory Affairs Manager

Preparation date of the 510(k) summary: 31. October 2005

2. Name of device:

Device Common name:	Manual Emergency Ventilator (Reusable)
Device Trade name:	Ambu® Mark IV Resuscitator
Classification Name:	Ventilator, Emergency, Manual (Resuscitator) 21 CFR 868.5915
Product Code:	BTM

3. Identifies the legally marketed device to which equivalence is claimed

Manufacturer	Trade Name	Product code
Ambu A/S	Ambu® SIR 2 (Silicone Resuscitator), Adult	BTM
Ambu A/S	Ambu® Mark III Resuscitator	BTM
Ambu A/S	Ambu® SPUR® II Adult	BTM

4. Description of device
   Ambu® Mark IV Resuscitator should only be used by persons trained in resuscitation. The use of the product is well known to trained users.
   Ambu® Mark IV Resuscitator is used for manual pulmonary resuscitation and emergency respiratory support of patients with a body weight of more than 33 lbs (15 kg), approx. 3 years of age.
   Ambu® Mark IV Resuscitator is a reusable device. The product can be cleaned after use according to the description in the direction for use.
   The product consists of a self-inflating double walled resuscitator bag, with a self-expanding inner bag and a thin-walled outer cover. The outer cover has an airtight connection to the neck of the inner bag supported by the connector in the patient valve end. At the opposite end of the bag the outer cover has an airtight connection with the inlet valve housing.
   The inlet valve allows ambient air or supplementary oxygen to flow into the bag and prevents air flowing backwards from the bag through the inlet valve during ventilation. An oxygen reservoir bag can be mounted to the Ambu® Mark IV Resuscitator.
   The patient valve housing is attached to the bag by a turn able airtight connection. The patient valve directs the ventilation air through patient connector into the patient airway and directs the patient expiration air through the expiration connector.
   The patient- and expiration connectors are standard connectors to avoid unsuitable connections with other devices.
   The patient connector, patient valve housing and inlet valve housing is made of hard plastic. The self-inflating bag is made of silicone rubber that can be squeezed by hand and returns to normal state when the hand is removed.
   The Ambu® Mark IV Resuscitator has an oxygen reservoir bag volume of 1500 ml. The stroke volume with one hand is > 600 ml and max. 1300 ml.

5. The intended use
   Ambu® Mark IV Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support. Ambu® Mark IV Resuscitator is intended for patients with a body weight of more than 33 lbs (15 kg), approx. 3 years of age.

6. Summary of the technological Characteristics
   The resuscitator bag has a double walled resuscitator bag. The patient valve directing the airflow to and from the patient. The inlet valve directs the air into the bag. An oxygen reservoir bag can be mounted to the product. The device is a reusable resuscitator.
   The technological characteristics of the Ambu® Mark IV Resuscitator are identical to one or more of the predicate devices in all of the products technological characteristics.

7. Brief discussion of the non-clinical tests submitted
   The non-clinical tests performed are laboratory tests to ensure that the product meets the recognized consensus standards for manual resuscitators. Ageing tests has been performed, the biocompatibility of the product has been established and comparison tests to predicate devices

have been performed.

8. Brief discussion of the clinical tests submitted
   No clinical tests are performed

9. Conclusions drawn from the non-clinical and clinical tests
   From the results of the non-clinical tests performed it has been concluded that Ambu® Mark IV Resuscitator has equivalent functionality as the predicate devices.
   It is concluded that Ambu® Mark IV Resuscitator is a safe and effective resuscitator and comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2005

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

Re: K053140
Trade/Device Name: Ambu® Mark IV Resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: November 8, 2005
Received: November 10, 2005

Dear Ms. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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):

Device Name: Ambu® Mark IV Resuscitator

Indications For Use:
Ambu® Mark IV Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support of patients with a body weight of more than 33 lbs (15 kg), approx. 3 years of age.
Ambu® Mark IV Resuscitator is a reusable resuscitator.

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 K033140