

DEC 20 2005

K053/42

## 510(k) Summary

1. 510(k) owner:

Ambu A/S  
Baltorpbakken 13  
2750 Ballerup  
Denmark  
Tel.: +45 72252000  
Fax.: +45 72252050

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 Baby 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

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Product code</u>
Ambu A/S	Ambu® Silicone Resuscitator, Infant/Child	BTM
Ambu A/S	Ambu® Baby R, Resuscitator model R	BTM
Ambu A/S	Ambu® SPUR® II Infant	BTM

4. Description of device

Ambu® Mark IV Baby Resuscitator should only be used by persons trained in resuscitation. The use of the product is well known to trained users. Ambu® Mark IV Baby Resuscitator is used for manual pulmonary resuscitation and emergency respiratory support of neonates, infants and children with a body weight of up to 44 lbs (20 kg), approx. 4-5 years of age.

Ambu® Mark IV Baby 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 tube reservoir can be mounted to the Ambu® Mark IV Baby 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.

A pressure-limiting valve (40 cm H<sub>2</sub>O) with an override mechanism is placed in patient valve housing.

The manometer port in patient valve housing enables connection to a manometer. When the manometer is not attached the manometer port is closed with a cap.

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 Baby Resuscitator has a 300 ml stroke volume.

5. The intended use

Ambu® Mark IV Baby Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support. Ambu® Mark IV Baby Resuscitator is intended for infants and children with a body weight up to 44 lbs (20 kg), approx. 4-5 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 tube reservoir can be mounted to the product. The device has a pressurelimiting valve (40 cm H<sub>2</sub>O). The manometer port in the patient valve housing enables connection to a manometer. The device is a reusable resuscitator.

The technological characteristics of the Ambu® Mark IV Baby 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 Baby Resuscitator has equivalent functionality as the predicate devices.

It is concluded that Ambu® Mark IV Baby Resuscitator is a safe and effective resuscitator and comparable to the predicate devices.



DEC 20 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K053142

Trade/Device Name: Ambu<sup>®</sup> Mark IV Baby Resuscitator  
Regulation Number: 21 CFR 868.5915  
Regulation Name: Manual Emergency Ventilator  
Regulatory Class: II  
Product Code: BTM  
Dated: November 8, 2005  
Received: November 9, 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.

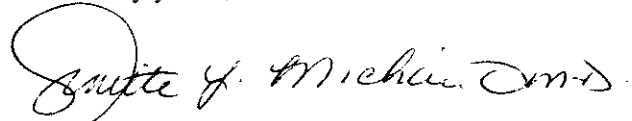
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K053142

Device Name: Ambu® Mark IV Baby Resuscitator

### Indications For Use:

Ambu® Mark IV Baby Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support of neonate, infants and children with a body weight up to 44 lbs (20 kg), approx. 4-5 years of age.

Ambu® Mark IV Baby Resuscitator is a reusable resuscitator.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of  1



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

510(k) Number  K053142