DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 29, 2016

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

Re: K152931
Trade/Device Name: Ambu SPUR II Adult Resuscitator
Ambu SPUR II Pediatric Resuscitator
Ambu SPUR II Infant Resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: June 26, 2016
Received: July 27, 2016

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 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K152931

Device Name
Ambu SPUR II Adult Resuscitator
Ambu SPUR II Pediatric Resuscitator
Ambu SPUR II Infant Resuscitator

Indications for Use *(Describe)*
The Ambu SPUR II resuscitator is a single patient use resuscitator intended for pulmonary resuscitation.
The range of application for each version is:
-Adult: Adults and children with a body weight more than 30 kg (66lbs).
-Paediatric: infants and Children with a body weights up to 30 kg (66lbs).
-Infant: Neonates and infant with a body weight up to 10kg (22lbs).

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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# Section 5 – 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

## 5.1 Submitter

Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
Tel.: +45 7225 2000
Fax.: +45 7225 2055

## 5.2 Contact Person

Name: Line Kagenow Svenstrup
Job Title: Regulatory Affairs Professional
Address: Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup
Telephone number: +45 7225 2217
Fax number: +45 7225 2055

## 5.3 Date summary Prepared

August 22, 2016

## 5.4 Device Trade name

Ambu SPUR II Adult Resuscitator
Ambu SPUR II Pediatric Resuscitator
Ambu SPUR II Infant Resuscitator

## 5.5 Device Common Name

Manual Resuscitator (Single Patient Use)

## 5.6 Classification name

Ventilator, Emergency, Manual (Resuscitator)

| | |
|---|---|
| Device Class: | II |
| Classification regulation: | 21 cfr 868.5915 |
| Product code: | BTM |
| The panel is: | Anesthesiology |

## 5.7 Legally Marketed Devices to which the device is substantially equivalent:

Ambu SPUR II Adult Resuscitator:

| Manufacturer | Trade Name | 510k number | Product code |
|---|---|---|---|
| AMBU A/S | Ambu® SPUR® II Adult | K042682 | BTM |

Ambu SPUR II Pediatric Resuscitator:

| Manufacturer | Trade Name | 510k number | Product code |
|---|---|---|---|
| AMBU A/S | Ambu® SPUR® II Pediatric | K042843 | BTM |

Ambu SPUR II Infant Resuscitator:

| Manufacturer | Trade Name | 510k number | Product code |
|---|---|---|---|
| AMBU A/S | Ambu® SPUR® II Infant | K042843 | BTM |

## 5.8 Description of the Device

Ambu SPUR II Resuscitator is intended for manual pulmonary resuscitation. It is a disposable device intended for Single Patient Use only.

Ambu SPUR II Resuscitator is available in three sizes: Adult, Pediatric and Infant.

The main components of the product are a patient valve, a bag, an inlet valve, a reservoir bag/tube and an oxygen tube.

The patient valve directs the ventilation air through a patient connector into the patient airway and directs the patient expiration air through an expiration connector. The patient connector is constructed to turn around its own axis enabling the resuscitator to turn in relation to connected masks or endotracheal tubes.

A pressure limiting valve (40 $cmH_2O$) with an override mechanism is placed in the patient valve housing of all Pediatric and Infant resuscitators. For the Adult resuscitators a pressure limiting valve is optional.

M-Port is mounted in the patient valve housing and provides access to the inspiratory and expiratory gas flow allowing connection of a syringe for drug delivery or a gas sampling line for measuring side stream $EtCO_2$. When the M-Port is not used it is

sealed with a cap and the resuscitator operates as a resuscitator without the M-Port. The M-Port is an optional feature.

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

The inlet valve allows ambient air to flow into the bag and prevents air flowing backwards from the bag through the inlet valve during ventilation.

The reservoir consists of either a reservoir bag (closed reservoir) or a reservoir tube (open reservoir) attached to the inlet valve.

Supplementary oxygen can be supplied through the oxygen tube attached to the oxygen connector (reservoir bag) or mounted inside the inlet valve assembly (reservoir tube). Supplementary oxygen flows into the reservoir attached to the inlet valve assembly.

A Face mask, Endotracheal Tube or Laryngeal Mask/Combitube can be connected to the patient connector of the resuscitator to ensure contact to the patient's airway.

The Ambu SPUR II Resuscitator complies with ISO 10651-4: Particular requirements for operator powered resuscitators.

## 5.9 Intended Use

The Ambu SPUR II resuscitator is a single patient use resuscitator intended for pulmonary resuscitation.

The range of the application for each version is:

- Adult: Adults and children with a body weight more than 30kg (66lb).
- Pediatric: Infant and children with a body weight up to 30kg (66lb).
- Infant: Neonates and infant with a body weight up to 10kg (22lb).

## 5.10 Summary of the technological characteristics in comparison to the predicate devices

Ambu SPUR II Resuscitator is substantially equivalent to:

- Ambu® SPUR® II Adult Resuscitator (K042682);
- Ambu® SPUR® II Infant & Pediatric Resuscitator (K042843)

There are the following differences between the predicate devices and the subject devices:

*Ambu SPUR II Resuscitator, All Sizes*

- The intended use of the subject devices does not include "emergency support" This use is thus covered by the term "pulmonary resuscitation" and the change will not affect the use of the products.
- The material of the bag has been changed. The change has been verified through bench testing and Biocompatibility Evaluation and does not affect the safety and performance of the resuscitators.
- Differences in standards used - ASTM F920-93 has been withdrawn without replacement. ISO 8382 has been replaced by ISO 10651-4:2009. ASTM

F1054-87 has been replaced by ISO 5356-1:2004. The New Ambu SPUR II Resuscitators also complies with EN 13544-2:2009.

- The Ambu SPUR II Resuscitators are MR Conditional. Magnetic Field Interaction Testing had been performed to confirm that the Resuscitator can be used in a MRI environment under certain conditions.

*Ambu SPUR II Resuscitator Adult*

- The M-port of the subject device has an additional function of EtCO2 (end tidal CO2) side stream measurement. On the predicate device, the M-port was used only for medication delivery. The product risk evaluation and verification of this design change indicate that adding of this function does not introduce any new risk to the product and will not affect the safety and effectiveness of the device.
- The following changes are only changes to the specifications given to the user; they do not have any impact on the design itself. The following specifications have been updated to show compliance with ISO 10651-4:2009:
    - The stroke volume specification
    - The dead space specification
    - The operating temperature

*Ambu SPUR II Resuscitator Pediatric and Ambu SPUR II Resuscitator Infant*

- The following change is only a change to the specifications given to the user; it does not have any impact on the design itself:
    - The expiratory resistance specification. This specification has been adjusted in order to fulfil the requirements from the Resuscitator Standard ISO 10651-4:2009.

The above differences have been evaluated and the conclusion is that they do not affect the performance and safety of the subject devices, the New Ambu SPUR II Resuscitator Adult, Pediatric and Infant, compared to the predicate devices in any undesirable way. The operation and technological characteristics of Ambu SPUR II Resuscitators are considered substantial equivalent to the predicate devices operation and technological characteristics. All devices have the same intended use.

Ambu concludes that the Ambu SPUR II Resuscitators are substantially equivalent to the predicate devices.

## 5.11 Performance Data – Bench

Ambu has demonstrated conformity with to the following recognized consensus standards;

- ISO 10651-4 Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators
- ISO 5356-1 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets

All tests have been performed as described in the standards.
Result: All tests were passed.

Connectors

- Patient connection port connector,
- Expiratory port connector for breathing gases
- Face mask connectors (connectors of facemask)

- Oxygen tube connector and pressure gauge connector

Operation requirements
- Patient valve function after contamination with vomits
- Mechanical shock
- Drop test
- Immersion in water

Ventilatory requirements
- Supplementary oxygen and delivered oxygen concentration
- Expiratory resistance
- Inspiratory resistance
- Patient valve malfunction
- Patient valve leakage – Forward leakage
- Resuscitator deadspace and rebreathing

Ventilation performance
- Minimum delivered volume
- Pressure limitation

Storage and Operation, tested at time zero and after accelerated aging
- Inspiratory/Expiratory resistance test
- Stroke volume test
- Patient valve malfunction test
- Supplementary oxygen and delivery oxygen concentration
- Pressure limitation test

Additional performance data was submitted to document the following properties of Ambu SPUR II:

CO2 monitoring
- Suitability of the M-port to be used for CO2 monitoring (accept criteria: Maximum deviation of 5% at a confidence level of 95% in comparison to the Philips Side Stream Adapter).

Result: Passed with at least 0.4 liter of tidal volume.

MR Conditional
- MR Conditional properties (Magnetic Field Interaction Testing was performed in according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment)

Result: Passed, Ambu SPUR II is MR Conditional and can be used in a MRI environment under specified conditions.

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)

In addition Extractable and Leachable (E&L) testing has been performed.

Result: All tests were passed

Since the device is in compliance with the listed standards and has passed the listed performance tests, it is concluded that technological characteristics of Ambu SPUR II is as safe and as effective as the currently marketed predicate devices.

## 5.12 Performance Data – Clinical

No Clinical tests are performed.

## 5.13 Conclusion

Based on the Intended use, operation and technological characteristics, and performance testing, it has been concluded that the Ambu SPUR II Adult Resuscitator, Ambu SPUR II Pediatric Resuscitator and Ambu SPUR II Infant Resuscitator is substantial equivalent to the predicate devices.

It is concluded that the Ambu SPUR II Adult Resuscitator, Ambu SPUR II Pediatric Resuscitator and Ambu SPUR II Infant Resuscitator are as safe and as effective as the legally marketed predicate devices.