DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 15, 2015

Laerdal Medical AS
Mari Kaada
Regulatory Affairs Manager
Tanke Svilandsgate 30
P.O. Box 377
4002 Stavanger
Norway

Re: K132172
Trade/Device Name: NeoNatalie resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual emergency ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: January 6, 2015
Received: January 7, 2015

Dear Ms. Kaada:

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" (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 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

Erin I. Keith, M.S.
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)*
K132172

Device Name
NeoNatalie Resuscitator

Indications for Use *(Describe)*
The NeoNatalie Resuscitator is a self-inflating, manual resuscitator intended for newborns and infants up to 5 kg body mass who require respiratory support.

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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510(k) Summary

Submitter's Name and Address

Mari Kaada
Corporate Regulatory Affairs Manager
Laerdal Medical AS
Tanke Svilandsgate 30
P.O. Box 377
4002 Stavanger
Norway
T: (011) 47-51-51-16-30
Fax: (011) 47-51-51-17-17
Mari.Kaada@laerdal.no

Date the 510(k) Summary was Prepared

14 January 2015

Device Name

Proprietary Name:	NeoNatalie Resuscitator
Common Name:	Manual Resuscitator (Reusable)
Classification Name:	Ventilator, Emergency, Manual (Resuscitator) (21 CFR 868.5915, Product Code BTM, Class II)

Predicate Devices

The legally marketed devices to which Laerdal Medical AS claims equivalence for the NeoNatalie Resuscitator are:

- Ambu® Mark IV Baby Resuscitator (Ambu A/S), K053142

Device Description

The NeoNatalie Resuscitator is a self-inflating, manual resuscitator intended for newborns and infants up to 5 kg body mass who require respiratory support.

A manual resuscitator is a resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device, the ventilation bag. The ventilation bag is self-inflating: the compressed bag will refill with ambient air via the bag inlet valve. The resuscitator provides positive pressure ventilation of the lungs (when used with a face mask). The resuscitator can be used to provide supplemental oxygen when used with the oxygen kit, the NeoNatalie Resuscitator Oxygen Kit. When a resuscitator fitted with an oxygen reservoir is used to provide supplemental oxygen, the ventilation bag will refill with oxygen from the oxygen reservoir.

The NeoNatalie Resuscitator is made of polysulfone, silicone rubber and stainless steel.

The NeoNatalie Resuscitator is reusable resuscitator which may be sterilized by autoclaving.

The NeoNatalie Resuscitator is intended for use by persons trained in the use of resuscitators.

Indication for Use

The NeoNatalie Resuscitator is a self-inflating, manual resuscitator intended for newborns and infants up to 5 kg body mass who require respiratory support.

Substantial Equivalence

The NeoNatalie Resuscitator and Oxygen Kit has the same intended use as the Ambu® Mark IV Baby Resuscitator (Ambu A/S), K053142. It has the same fundamental design, method of use (ventilation via mask, bag, and optional oxygen reservoir) and similar materials to the predicate device. The following table compares the NeoNatalie Resuscitator with the predicate device with respect to indication and technological characteristics.

	NeoNatalie Resuscitator (this 510(k))	**Ambu® Mark IV Baby Resuscitator (K053142)**
Indication	The NeoNatalie Resuscitator is a self-inflating, manual resuscitator intended for newborns and infants up to 5 kg body mass who require respiratory support.	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), approximately 4-5 years of age.
Parts	• Two circular masks • Self-inflating ventilation bag • Patient valve • Oxygen kit (Oxygen Reservoir Bag, Valve and Tubing)	• Patient valve with pressure relief valve • Ventilation bag • Inlet valves • Oxygen tube
Materials	• Polysulfone • Silicone rubber • Stainless steel (spring)	• Silicone rubber • Polysulfone • Reinforced polypropylene • Ethylene propylene diene monomer rubber • Polyoxymethylene • Polyethylene • Polyethersulfone • Thermoplastic polyurethane • Stainless steel • Aluminum
Expiratory Resistance	< 2.5 cmH_2O at 5 LPM	0.6 cmH_2O at 5 LPM
Inspiratory Resistance	< 0.5 cmH_20 at 5 LPM	0.5 cmH_2O at 5 LPM
Dead Space	4 ml	< 6 mL

Data Used in Determination of Substantial Equivalence

Design verification and design validation testing demonstrates that the NeoNatalie Resuscitator meets its functional requirements and performance specifications. In particular,

- Biocompatibility testing in accordance with FDA guidance, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* (Blue Book Memo G95-1, May 1, 1995). Testing of the patient contacting part and three indirect patient contact parts of the NeoNatalie Resuscitator demonstrate an applicable biocompatibility profile for the device,
- Testing in accordance with ISO 10651-4:2002 *Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators* demonstrates compliance with the standard with only minor deviations,
- Testing in accordance with ISO 5356-1:2004 *Anesthetic and respiratory equipment - Conical connectors – Part 1: Cones and sockets* demonstrates compliance with the standard with only minor deviations ,
- Testing has demonstrated that the device can be high level disinfected by the reprocessing instructions given in the device labeling.
- Testing has demonstrated that the device meet performance criteria after repeated reprocessing

Conclusion

Based on the results of the testing and other information submitted in the 510(k) application, the NeoNatalie Resuscitator does not raise any different questions regarding the safety or effectiveness compared to the predicate device. Further, the device was tested based on accepted scientific methods and the performance data demonstrate substantial equivalence; therefore, the NeoNatalie Resuscitator is considered to be as safe and effective.