K102542

510(k) Summary

27-Mar-11

APR - 6 2011

Atom Medical Corporation
3-18-15, Hongo, Bunkyo-ku
Tokyo, Japan 113-0033

Tel – 011-81-3-3815-3632
Fax – 011-81-3-3812-3199

Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: Resusci Flow series resuscitator

Common/Usual Name: Infant Resuscitator

Classification Name/Code: BTL – powered emergency ventilator
CFR 868.5925

Device: Resusci Flow
Resusci Flow and blender
Resusci Flow 104 EV
Resusci Flow 104 PV

Predicate Devices: GE – Giraffe and Panda – K070210
Fisher & Paykel – NeoPuff – K892885

Device Description:
There are four (4) models of the Resusci Flow resuscitator.

- Resusci Flow
- Resusci Flow with blender
- Resusci Flow 104PV
- Resusci Flow 104EV

They all have the same basic design. **Table 1** outlines the basic features and differences of each model.

Table 1 Resusci Flow Series

Feature	Resusci Flow	Resusci Flow with Blender	Resusci Flow 104PV	Resusci Flow 104EV
PIP (Peak Inspiratory Pressure)	Yes	Yes	Yes	Yes
Suction(Piping Type)	No	No	Yes	No
Suction(Venturi Type)	No	No	No	Yes
Oxygen / Air Mixture	No	Yes	Yes	Yes
Inlet Gas Sources	Mixture of oxygen and air	Oxygen compression gas Air compression gas	Oxygen compression gas Air compression gas Suction compression gas	Oxygen compression gas Air compression gas
Pressure Relief Valve	Yes	Yes	Yes	Yes
Pressure Gauge	Yes	Yes	Yes	Yes
Suction Pressure Gauge	No	No	Yes	Yes
Outlet	Single outlet	Single outlet	Double outlets (Outlet A/B)	Double outlets (Outlet A/B)
	This outlet is for resuscitation using aerosol tube and "T" Flow Valve. It may be connected a face mask or tracheal tube.		Outlet A is for resuscitation using aerosol tube and "T" Flow Valve. It may be connected a face mask or tracheal tube. Outlet B can be connected to oxygen tent, oxygen mask, oxygen cannula and humidifier jar etc.	
Predicates	Fisher & Paykel RD1000 NEOPUFF INFANT RESUSCITATOR (K892885)	Giraffe and Panda T-piece Resuscitation System (K070210)		

Indications for Use:
The Resusci Flow series (Resusci Flow and Resusci Flow with blender) is a manually operated ventilator intended to assist a doctor in resuscitating an infant who has spontaneous breathing by providing the positive end-expiratory pressure (PEEP) and the peak inspiratory pressure (PIP).

The Resusci Flow series (Resusci Flow 104 PV and Resusci Flow 104EV) is intended for resuscitation of neonates in a delivery room and a NICU. It is used to remove secretions from the neonatal mouth and nostrils or to ventilate or assist in ventilating neonates suffering from apnea or other respiratory failure.

All are intended for neonates and infants (< 10kg or 22 lbs) in a delivery room and a NICU.

Environment of Use: Hospitals, delivery suites, NICU

Summary of substantial equivalence

Resusci Flow

The Resusci Flow model was compared to the predicate Fisher & Paykel NeoPuff (K892885) and found to be substantially equivalent based upon:

Indications for Use – The Resusci Flow has equivalent indications for use to the predicate.

The details of the NeoPuff indications are not available, except in their labeling due to the age of the clearance, 1989. Nonetheless the indications for use are equivalent.

Patient Population – The Resusci Flow has the equivalent patient population neonates and infants. We have been more specific than the predicate NeoPuff and included a limitation of patient weight.

Environment for use – The Resusci Flow has the identical environments for use as the predicate.

Prescriptive – The Resusci Flow is identical to the predicate.

Design and Technology – The Resusci Flow has an equivalent design and features as the predicate and has the identical technology as the predicate.

Performance and Specifications – The Resusci Flow has equivalent specifications of performance as the predicate.

Compliance with standards – Both devices declare compliance with the internal standard ISO 10651-5 for powered resuscitators.

Conclusion

The Resusci Flow is substantially equivalent to the predicate NeoPuff (K892885) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

Resusci Flow with Blender, Resusci Flow 104 PV and Resusci Flow 104 EV

The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV were compared to the predicate GE Giraffe and Panda T-piece resuscitator (K070210). As well as the Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV were compared to the predicate GE Giraffe and Panda (K070210) for equivalence.

Indications for Use – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV have equivalent indications for use to the predicate.

Patient Population – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV have the equivalent patient population neonates and infants.

Environment for use – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV have the identical environments for use as the predicate.

Prescriptive – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV are identical to the predicate.

Design and Technology – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV have an equivalent design and features as the predicate and has the identical technology as the predicate.

Performance and Specifications – The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV have equivalent specifications of performance as the predicate.

Compliance with standards – Both devices declare compliance with the internal standard ISO 10651-5 for gas powered resuscitators and ISO 10079-3 for suction equipment.

Conclusion
The Resusci Flow with Blender, Resusci Flow 104PV, and Resusci Flow 104EV is substantially equivalent to the predicate GE Giraffe and Panda (K070210) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

Performance Testing

We have performed bench tests which included the list below and found that the Resusci Flow series (Resusci Flow, Resusci Flow with blender, Resusci Flow 104 PV, and Resusci Flow 104 EV) resuscitators met all pass /fail criteria, cited standards requirements or were found to be equivalent in comparison to the predicates.

- ISO 10651-5 clause 5.1.10 Display accuracy of the airway pressure gauge
- Gas discharge flow rate from the patient circuit
- ISO 10651-5 Clause 7.7.1 Delivered concentration accuracy of oxygen
- ISO 10651-5 clause 7.1.2.2 Inspiratory resistance
- ISO 10651-5 clause 7.2.4 pressure limitation
- ISO 10651-5 clause 7.2.4 and 5.1.10 Pressure characteristics of peak inspiratory pressure (PIP inspiratory resistance)
- Confirm the maximum open pressure (Pmax)
- ISO 10651-5 clause 7.2.4 and 5.1.10 positive end-expiratory pressure (PEEP)
- Environment Performance
- Vibration Testing
- Drop Testing
- Test pressure loss alarm
- ISO 11195 Gas mixers alarm for loss of pressure
- ISO 10079-3 for suction equipment
- Safety requirements
- Vomitus Resistance
- Expiratory Resistance

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

Atom Medical Corporation
C/O Mr. Paul Dryden
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

APR - 6 2011

Re: K102542
Trade/Device Name: Resusci Flow Series, Resusci Flow, Resusci Flow with Blender, Resusci Flow 104 PV and Resusci Flow 104 EV
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: March 27, 2011
Received: March 29, 2011

Dear Mr. Dryden:

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,

Anthony 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 Statement

510(k) Number: K102542

Device Name: Resusci Flow series
Resusci Flow
Resusci Flow with blender
Resusci Flow 104 PV
Resusci Flow 104 EV

Indications for Use:

The Resusci Flow series (Resusci Flow and Resusci Flow with blender) is a manually operated ventilator intended to assist a doctor in resuscitating an infant who has spontaneous breathing by providing the positive end-expiratory pressure (PEEP) and the peak inspiratory pressure (PIP).

The Resusci Flow series (Resusci Flow 104 PV and Resusci Flow 104EV) is intended for resuscitation of neonates in a delivery room and a NICU. It is used to remove secretions from the neonatal mouth and nostrils or to ventilate or assist in ventilating neonates suffering from apnea or other respiratory failure.

All are intended for neonates and infants (≤ 10kg or 22 lbs) in a delivery room and a NICU.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

J Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102542