K103317

**510(k) Summary**
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**Official Contact:** Tsuyoshi Sugino – Regulatory Affairs Manager

**Proprietary or Trade Name:** Resuscitation Unit 105

**Common/Usual Name:** Air / oxygen blender

**Classification Name/Code:** BZR – Breathing gas mixer
CFR 868.5330

**Device:** Resuscitation Unit 105EV
Resuscitation Unit 105PV

**Predicate Devices:** Bio-Med Devices – BMD air/oxygen blender – K925982
~~Precision Medical – Precision Blender – K053232~~
Atom Medical – V-505 Infant Warmer – K060461
GE Giraffe and Panda system – K070210

**Device Description:**
There are two (2) models of the Resuscitation Unit 105 air / oxygen blender with suction.

- Resuscitation Unit 105PV
- Resuscitation Unit 105EV

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

**Indications for Use:**
The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are intended to remove secretions from the neonatal / infant airways and / or to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent.

**Environment of Use:** Hospitals, delivery suites, NICU

**Table 1 Resuscitation Models 105PV and 105EV**

| Feature | Resuscitation Unit 105PV | Resuscitation Unit 105EV |
|---|---|---|
| Suction(Piping Type) | Yes | No |
| Suction(Venturi Type) | No | Yes |
| Oxygen / Air Blender | Yes | Yes |
| Inlet Gas Sources | Oxygen compressed gas<br><br>Air compressed gas<br><br>Suction compressed gas | Oxygen compressed gas<br><br>Air compressed gas |
| Pressure Relief Valve | Yes | Yes |
| Pressure Gauge | Yes | Yes |
| Suction Pressure Gauge | Yes | Yes |
| Outlet | Double outlets<br>(Outlet A/B) | Double outlets<br>(Outlet A/B) |
| | Outlet A / B is for delivery of the air/oxygen gas mixture to a variety of devices, i.e., oxygen tent, oxygen mask, nasal cannula, manual resuscitator or manual ventilator, in-line humidifier jar, etc.<br><br>Airway Pressure tube and adapter can be connected at the patient connected to measure and monitor the airway pressure which is displayed on the integral pressure gauge as well as a pressure regulating valve. | |

As outlined in **Table 1**, the Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are identical except for the source for vacuum. Model 105PV is from a wall vacuum source and Model 105EV is from an internal venturi.

**Table 2** compares the Resuscitation Unit 105 EV and Resuscitation Unit 105 PV to the predicates:

- Atom V-505 Infant warmer with optional oxygen / suction module (K060461)
- Bio-Med Devices – BMD air/oxygen blender (K925982) a blender which is incorporated into the proposed devices
- Precision Medical – Precision Blender (K053232) which has the indications for use and product classification we are seeking.

**Table 3** compares the Resuscitation Unit 105 EV and Resuscitation Unit 105 PV to the predicates Atom V-505 Infant warmer with optional oxygen / suction module (K060461) and the GE Giraffe and Panda system (K070210) which incorporates suction function and features for the intended patient population and environment.

## Table 2 – Resuscitation Unit 105PV and Unit 105EV
## Table of the Similarities and Differences to the Predicates for Air / Oxygen Blender features

| | **Resuscitation Unit Unit 105PV Unit 105EV** | **Atom V-505 Infant Warmer with oxygen / suction module K060461** | **Bio-Med Devices BMD air/oxygen blender K925982** | **Precision Medical Precision Blender K053232** |
|---|---|---|---|---|
| **General Attributes** | | | | |
| Indications for Use | The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are intended to remove secretions from the neonatal / infant airways or to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent. | The blender and suction modules incorporated in the V-505 Infant Warmer are intended to remove secretions from the neonatal / infant airways or to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent. | There is no indications for sue statement in the FDA database but the BMD air/oxygen blender is intended to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% | Is intended to deliver blended air and oxygen in a hospital setting. Oxygen concentrations can be dialed in from 21 to 100%. The blender is not intended as a life supporting device. |
| Patient Population | Neonates and Infants | Neonates and Infants | Not specified | Not specified |
| Environment of Use | Hospital, delivery suites, NICU | Hospital, delivery suites, NICU | Hospital, delivery suites, NICU | Hospital setting |
| Prescriptive | Yes | Yes | Yes | Yes |

| | **Resuscitation Unit Unit 105PV Unit 105EV** | **Atom V-505 Infant Warmer with oxygen / suction module K060461** | **Bio-Med Devices BMD air/oxygen blender K925982** | **Precision Medical Precision Blender K053232** |
|---|---|---|---|---|
| **General Attributes (continued)** | | | | |
| Outlet connections to | Oxygen tent<br>Oxygen mask<br>Cannula<br>Manual ventilator<br>Manual resuscitator | Oxygen tent<br>Oxygen mask<br>Cannula<br>Manual ventilator<br>Manual resuscitator | Oxygen tent<br>Oxygen mask<br>Cannula<br>Manual ventilator<br>Manual resuscitator | Oxygen tent<br>Oxygen mask<br>Cannula<br>Manual ventilator<br>Manual resuscitator |
| Accessories /Components | Airway pressure tube<br>Hoses and tubing<br>Humidifier jar<br>Suction jar | Hoses and tubing<br>Humidifier jar<br>Suction jar | None supplied | None supplied |
| **Technical specifications** | | | | |
| **Oxygen / air supply module** | | | | |
| Gas sources<br>input pressure | Air/$O_2$<br>300-500kPa | Air/$O_2$<br>206-517kPa | Air/$O_2$<br>206-517kPa | Air/$O_2$<br>206-517kPa |
| Airway pressure manometer<br>Range Accuracy | -20 to 80cm$H_2O$<br>$\pm$1% of full scale | N/A | N/A | N/A |
| Air/$O_2$ blender<br>Range<br>Accuracy | 21-100%<br>$\pm$3%$O_2$ | 21-100%<br>$\pm$3%$O_2$ | 21-100%<br>$\pm$3%$O_2$ | 21-100%<br>$\pm$3%$O_2$ |
| Alarm | Differential pressure between oxygen and air supply | Differential pressure between oxygen and air supply | Differential pressure between oxygen and air supply | Differential pressure between oxygen and air supply |
| Bleed flow rate | 2.5 – 3.5 lpm | 2.5 – 3.5 lpm | N/A | N/A |
| Gas flow rate range | $\leq$ 15 lpm | $\leq$ 15 lpm | $\geq$ 30 lpm | $\geq$ 30 lpm |

| | **Resuscitation Unit Unit 105PV Unit 105EV** | **Atom V-505 Infant Warmer with oxygen / suction module K060461** | **Bio-Med Devices BMD air/oxygen blender K925982** | **Precision Medical Precision Blender K053232** |
|---|---|---|---|---|
| **Technical specifications (continued)** | | | | |
| Relieving valve (for preventing excessive airway pressure) | (Default setting : 5.9kPa (60cmH2O)) | N/A (no reliving valve) | N/A(no relieving valve) | N/A(no relieving valve) |
| Flow outlet | Dual flow outlet to connect to a device requiring a gas supply<br>Oxygen density of both is the same. | Single flow outlet to connect to device requiring a gas supply | Flow outlet for connecting to device requiring a gas supply | Flow outlet for connecting to device requiring a gas supply |
| **Standards** | | | | |
| ISO 10651-5 Gas powered resuscitators | Yes, applicable sections | N/A | N/A | N/A |
| ISO 10079-3 suction equipment | Yes, applicable sections | N/A | N/A | N/A |
| Section 514 | None | None | None | None |

## Table 3 – Resuscitation Unit 105PV and 105EV
## Table of the Similarities and Differences to the Predicates for Suction features

| | **Resuscitation Unit Unit 105PV Unit 105EV** | **Atom V-505 Infant Warmer with oxygen / suction module K060461** | **GE Giraffe and Panda K070210** |
|---|---|---|---|
| **General Attributes** | | | |
| Indications for Use | The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are intended to remove secretions from the neonatal / infant airways and to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent. | The blender and suction modules incorporated in the V-505 Infant Warmer are intended to remove secretions from the neonatal / infant airways and to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent. | Provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen and air/oxygen mixtures and/or manual ventilation to the infant. (Includes a suction function and feature) |
| Patient Population | Neonates and Infants | Neonates and Infants | Infant |
| Environment of Use | Hospital, delivery suites, NICU | Hospital, delivery suites, NICU | Hospital, delivery suites, NICU |
| Prescriptive | Persons trained in infant / neonate resuscitation | Persons trained in infant / neonate resuscitation | Persons trained in infant / neonate resuscitation |
| **Technical specifications** | | | |
| Suction bottle capacity | Up to 1200 ml | Not specified | Not specified other than various sizes |
| Dimensions<br>Weight | 200mm(W)x180 mm(D)x370mm (H)<br>7kg | Built-in to warmer, not standalone | 340mm(W)x250mm(D)x250mm(H)<br>9 kg |
| Operating and Storage limits | -20°C to 65°C<br>Up to 97% RH | -20°C to 65°C<br>Up to 97% RH | -20°C to 60°C<br>Up to 95% RH |

| | **Resuscitation Unit Unit 105PV Unit 105EV** | **Atom V-505 Infant Warmer with oxygen / suction module K060461** | **GE Giraffe and Panda K070210** |
|---|---|---|---|
| **Technical specifications (continued)** | | | |
| Vacuum source | Model 105PV – wall suction vacuum<br>Model 105EV – venturi method | Model 105PV – wall suction vacuum | Wall suction vacuum |
| Vacuum range | 0-200 mmHg | 0-200 mmHg | 0-150 mmHg |
| Vacuum Flow range | ~ 20 lpm | N/A | 15 lpm |
| **Standards** | | | |
| ISO 10651-5 Gas powered resuscitators | Yes, applicable sections | N/A | Yes, applicable sections |
| ISO 10079-3 – Suction equipment | Yes, applicable sections | N/A | Yes, applicable sections |
| Section 514 | None | None | None |

**Summary of substantial equivalence - Resuscitation Unit 105PV and Resuscitation Unit 105EV**

**Indications for Use** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV have equivalent indications for use to the predicates. That is as a breathing gas mixer (blender) with a suction feature.

**Patient Population** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV have the equivalent patient population, neonates and infants, to the predicate V-505 Infant warmer module (K060461) and GE Giraffe and Panda system (K070210).

**Environment for use** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV have the identical environments for use to the predicates K060461, K053232, and K070210.

**Prescriptive** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are prescriptive which is identical to the predicates K060641, K053232, and K070210.

**Design and Technology** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are equivalent in design and features to the predicates and have the equivalent technology as the predicates.

Blender module is equivalent to V-505 Infant Warmer (K060461) and identical to Bio-Med Device (K925982).

Suction module is equivalent to V-505 Infant Warmer (K060461) and equivalent to GE Giraffe and Panda system (K070210).

**Performance Specifications** – The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV have equivalent specifications of performance to the predicate K060461.

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

**Performance Testing**

We have performed bench tests which included the list below and found that the Resuscitation Unit 105 EV and Resuscitation Unit 105 PV met all pass /f ail criteria, cited standards requirements or were found to be equivalent in comparison to the predicates.

We have performed the following performance testing. The results demonstrated that the device perform as intended. The tests are:

- Flow accuracy
- Pressure gauge accuracy
- ISO 10651-5 $O_2$ concentration
- ISO 10079-3 5.1.4 – Suction, 3 6.1 – Overfill, 6.3.1.1 – Suction seal, 8.4.3 and 9.1 – Aspiration, 6.5 – Pressure, 9.1 – External gas source, 8.1 – suction equipment, 6.11 – Noise
- ISO 11195 – Alarm

**Conclusion**

The Resuscitation Unit 105 EV and Resuscitation Unit 105 PV are substantially equivalent to the predicates Atom V-505 Infant warmer with oxygen / suction module (K060461) and the Bio-Med Devices – BMD air/oxygen blender (K925982) as the blender which is incorporated into the proposed devices and the Precision Medical – Precision Blender (K053232) in indications for use, patient population, and environment for use, and GE Giraffe and Panda systems for the suction feature (K070210). All of the predicates have equivalent technology characteristics, specifications / performance and compliance with international standards.

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 E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

APR 20 2011

Re: K103317
Trade/Device Name: Resuscitation Unit 105PV & Resuscitation Unit 105EV
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: April 8, 2011
Received: April 13, 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,

for

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:** K103317

**Device Name:** Resuscitation Unit 105PV
Resuscitation Unit 105 EV

**Indications for Use:**

The Resuscitation Unit 105 PV and Resuscitation Unit 105 EV are intended to remove secretions from the neonatal / infant airways and to provide blended air and oxygen at a desired oxygen concentration in the range of 21-100% to a respiratory assist device connected to the patient such as a ventilator (including a manually operated one) and an oxygen tent.

Environment of use – Hospitals, delivery suites, NICU

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

(Division Sign-Off)
Division of Anesthesiology, General Hosp
Infection Control and Dental Devices
510(k) Number: K103317