5.0 510(k) Summary K 112852

JAN 13 2012

Date: December 12, 2011

Owner:

A Plus Medical
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Owner/Operator Number:

10023166

Official Contact:

Thomas C. Loescher
Tel: + 760-930-4025
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Trade Names:

Babi.Plus™ Neonatal Resuscitation Bag
Babi.Plus™ N Bag

Common/Usual Name:

Manual Resuscitation Bag

Classification Name:

Device Name:	Ventilator, Emergency, Manual (Resuscitator
Product Code:	BTM
Regulation:	CFR 868.5915
Device Class:	II

Device:

Babi.Plus™ Neonatal Resuscitation Bag

Predicate Devices:

Number:	K082092
Product Name:	Dispo – Manual Resuscitation Bag
Manufacturer:	GaleMed Corporation
Product Codes:	2328

Device Description:

Single patient use medical device, which temporarily augment ventilation during ventilatory insufficiency or ventilatory failure.

Indications for Use:

Single patient use manual resuscitation device to temporary ventilate neonate, newborn or infant with a body mass of less than or equal to 3.3 Kg in hospital, transport, emergency and post hospital care environments.

Contraindications:
Body mass greater than 3.3 Kg.

Patient Population:
Patient populations of neonate, newborn or infant with a body mass of less than or equal to 3.3 Kg.

Environment of Use:
Hospital, transport, emergency and post hospital care environments

Comparative of Technological Characteristics:
Babi.Plus™ and predicate products conform to requirements set forth in ISO 10651-4:2002 entitled "Lung ventilators – Part 4: Particular requirements for operator powered resuscitators". A summary of critical performance attributes include:

Item	**Babi.Plus™**	*Predicate*
Patient Connector:	15 mm I.D.	15 mm I.D. / 22 mm O.D.
Face Mask:	Option offered, 15 mm O.D.	Option offered, 15 mm O.D.
Pressure Gauge Connector:	4.0 mm O.D. tapered	None
Supplemental oxygen delivery:	V_T – 20 mls, Rate – 60 BPM: @ 2 LPM – 91%, @ 10 LPM – 99$^+$% V_T – 20 mls, Rate – 120 BPM: @ 2 LPM – 91%, @ 10 LPM – 99$^+$% V_T – 50 mls, Rate – 30 BPM: @ 2 LPM – 75%, @ 10 LPM – 99$^+$% V_T – 50 mls, Rate – 60 BPM: @ 2 LPM – 66%, @ 10 LPM – 99$^+$%	V_T – 20 mls, Rate – 60 BPM: @ 2 LPM – 82%, @ 5 LM – 97% @ 10 LPM – 98$^+$% @ 15 LM – 99$^+$% V_T – 150 mls, Rate – 25 BPM: @ 2 LPM – 50% @ 5 LM – 96% @ 10 LPM – 98$^+$% @ 15 LM – 99$^+$%
Expiratory resistance:	< 1.7 cm H_2O @ 5 LPM	< 2.8 cm H_2O @ 5 LPM
Inspiratory resistance:	< 1.3 cm H_2O @ 5 LPM	< 2.8 cm H_2O @ 5 LPM
Patient Valve malfunction:	< 6.0 cm H_2O @ 30 LPM	< 6.0 cm H_2O @ 30 LPM
Dead space:	6.35 mls	6.8 mls
Minimum / Maximum Volume:	20 mls / 50 mls	20 mls / 150 mls
Body mass range:	≤ 3.3 Kg	≤ 10.0 Kg
Pressure limitation:	25 cm H_2O ± 3.0 cm H_2O with 40 cm H_2O ± 5.0 cm H_2O over-ride	40 cm H_2O ± 5.0 cm H_2O with over-ride, unlimited pressure

Conclusion:
Babi.Plus™ Neonatal Manual Resuscitation bags are substantially equivalent in indication for use, environment of use, patient population design, material and function of the identified predicate.

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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

Mr. Thomas C. Loescher
President
A Plus Medical
5431 Avenida Encinas, Suite G
Carlsbad, California 92008

JAN 13 2012

Re: K112852
Trade/Device Name: Babi Plus™ Neonatal Resuscitation Bag
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: December 12, 2011
Received: December 13, 2011

Dear Mr. Loescher:

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 D. 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: _____ (To be assigned)

Device Name: **Bebi.Plus™** Neonatal Resuscitation Bag

Indications for Use:

Single patient use manual resuscitation device to temporary ventilate neonate, newborn or infant with a body mass of less than or equal to 3.3 Kg in hospital, transport, emergency and post hospital care environments.

Prescription Use X **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 Hospital
Infection Control, Dental Devices

510(k) Number: K112852