K090317

A Plus Medical
Solutions for Respiratory Care

510(k) Summary

MAY 20 2009

Owner:

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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 Bubble PAP Valve

Common/Usual Name:

PEEP Valve, CPAP Valve, PAP Valve, Bubble CPAP

Classification Name:

Device Name:	Attachment, Breathing, Positive End expiratory Pressure
Product Code:	BYE
Regulation:	868.5965
Device Class:	2

Device:

Babi*Plus Bubble CPAP Valve

Predicate Devices:

Number:	Preamendment device
Product Name:	Water Seal PEEP Valve
Manufacturer:	unknown – believed to be McGaw Laboratories
Product Codes:	Unknown
Number:	K082092
Product Name:	Disposable PEEP Valve
Manufacturer:	GaleMed Corporation
Product Codes:	2421 – 2425, inclusive and 2461 – 2481, inclusive
Number:	K902062
Product Name:	Disposable PEEP Valve
Manufacturer:	Hudson RCI, Temecula, CA (Teleflex Medical, Research Triangle Park, NC)
Product Codes:	LIFESAVER® PEEP Valve Models 5383 and 5385

Device Description:

Single patient use water seal positive end expiratory pressure device.

Indications for Use:

The ***Babi*Plus*** Bubble PAP Valve is a single patient use positive end expiratory pressure valve for use with infant patients weighing < 10 Kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

Contraindications:

Contraindicated in individuals not requiring elevated lung pressure therapy.

Patient Population:

Patient populations from neonate to infant.

Environment of Use:

Hospital

Comparative of Technological Characteristics:

The A Plus Medical ***Babi*Plus*** Bubble PAP Valve is substantially equivalent in indications for use, environment of use, patient population, material and function to the identified predicate and to devices that were in the market before 1976 and/or the post 1976 identified predicates. The A Plus Medical ***Babi*Plus*** Bubble PAP Valve and identified predicate device meet the requirements set forth ISO 5356- 1:2004 entitled "*Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets*". Bench testing confirmed the accuracy of the A Plus Medical ***Babi*Plus*** Bubble PAP Valve and predicate device at gas flows from 1 to 12 liters per minute.

Conclusion:

The A Plus Medical ***Babi*Plus*** Bubble PAP Valve is substantially equivalent to the predicate device and devices that were in the market before 1976 post 1976 identified predicates. The A Plus Medical ***Babi*Plus*** Bubble PAP Valve and all identified predicates have substantially equivalent performance. Both devices are made from substantially equivalent material, intended use and patient populations. The A Plus Medical ***Babi*Plus*** Bubble PAP Valve is limited to use in acute hospital critical facilities and is contraindicated in individuals not requiring elevated end expiratory pressure, gas flows over 12 LPM, patient transport or non hospital use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

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

Re: K090317
Trade/Device Name: *Babi*Plus* Bubble PAP Valve
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: April 24, 2009
Received: April 28, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(a)

Indications for Use Statement

510(k) Number: **K090317**

Device Name: ***Babi*Plus*** Bubble PAP Valve

Indications for Use: The ***Babi*Plus*** Bubble PAP Valve is a single patient use positive end expiratory pressure valve for use with infant patients weighing < 10 Kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

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: K090317