K110383

5.0. 510(k) Summary of Safety and Effectiveness Information

AUG - 1 2011

Date: May 25, 2011

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Official Contact:
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Trade Names:
The **Babi.Plus™** Pressure Limitation Manifold

Common/Usual Name:
Pressure Relief Valve Manifold

Classification Name:
Device Name: Ventilator, non-continuous (respirator)
Product Code: BZD
Regulation: 868.5905
Device Class: II

Device:
Babi.Plus™ Pressure Limitation Manifold

Predicate Devices:
K Number: K093716
Product Name: Infant Nasal Cannula System
Manufacturer: A Plus Medical
Product Codes: 20216 & 20217

K Number: K040366
Product Name: BC110 Pressure Manifold
Manufacturer: Fisher & Paykel Healthcare
Product Codes: BC110 & BC110-17

Device Description:
The **Babi.Plus™** single patient use Pressure Limitation Manifold is an accessory to the **Babi.Plus™** Infant Nasal Cannula System cleared for sale in K093716. The device is designed to protect patients up to 10 Kg from excessive pressure should a downstream occlusion occur in a positive pressure breathing system. The device is offered in 10 cm H_2O, 12.5 cm H_2O and 15 cm H_2O pressure relief valve configurations. The device is supplied with oxygen senor port, fresh gas inlet and a 1 meter length of gas supply tubing. The device consists of a four-way tee connector molded in a rigid plastic to which a pressure relief valve is mounted on the vertical axis, the fresh gas inlet and oxygen senror port are located adgacent to each other on the hporzontial axis. The device relieves pressure cause by an occlusion before the expiratory port and automatically resets upon correction of the occlusion. The outlet port of the device is a 22 mm inside diameter connection in compliance with ISO 5356-1, Version 3.

Indications for Use:

Single patient use device intended for neonate, infant or child with a body mass of less than 10 Kg requiring a pressure limitation system to eliminate excessive pressure should an obstruction occur between gas supply and exhalation port during continuous gas flow therapy up to 12 liters per minute in hospital critical care unit.

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Contraindications:
Body mass >10 Kg
Gas flows > 12 liters per minute.

Patient Population:
Neonate (premature infant), infant and children with a body mass of less than or equal to (≤) 10 Kg.

Environment of Use:
Hospitals and Patient Transport

Comparative Table of Technological Characteristics:

Item	Bebi.Plus™ Pressure Limitation Manifold	Predicate K093716	Predicate K040366
Gas Supply Inlet:	5.0 mm Gas Inlet	10 mm Tubing Connector	5.0 mm Gas Inlet
Gas Flow Range:	Less than 12 LPM	Less than 12 LPM	Less than 15 LPM
Oxygen Senor Port:	Present	None	Present
Pressure Monitoring Port:	None	Proximal Port	Present
Pressure Limitation:	Fixed 10.0 cm H_2O Fixed 12.5 cm H_2O Fixed 15.0 cm H_2O	None	Variable with flow: 17.5 cm H_2O @ 8 LPM
Intend Use:	Elimination of excessive pressure should an obstruction occur between gas supply and exhalation port during continuous gas flow therapy.	Gas delivery via nasal prong interface during intermittent or continuous gas flow therapy.	Pressure relief in case of downstream obstruction in circuit.
Location in Circuit – "dry side" of humidifier inlet	"Dry side" of humidifier (humidifier inlet)	"Wet side" of humidifier (near patient)	"Dry side" of humidifier (humidifier inlet)

Non-Clinical Tests Performed
The following bench testing has been performed on the Bebi.Plus™ Pressure Limitation Manifold to document performance and claims of this application:

1. Accelerated shelf-life testing, simulating a one (1) year shelf life.
2. Accuracy of pressure relief for each offered configuration at gas flow rates of one (1) to fifteen (15) liters per minute, dry air.
3. Service life testing of twenty eight (28) days at a gas flow rate of 15 LPM simulating a downstream obstruction twelve (12) times per hour.

Clinical and/or Animal Tests Performed:
No clinical testing was performed on any human; no testing was performed on any animal.

Safety, Effectiveness and Performance
Bebi.Plus™ Pressure Limitation Manifold ranges are based on clinical practice guidelines[1] and allows the clinician to determine the appropriate pressure limitation valve. Additionally, the each Pressure Limitation Manifold is tested at the time of manufacture at the minimum, mean and maximum gas flow rates to assure accuracy. The construction of the valve does not allow adjustment by the clinician. Each device is provided with a precise Instruction for Use and id clearly labeled as a "single patient use, not intended for reprocessing or use on multiple patients. Additionally the pressure relief value is clearly marked on the device using specific colors and indicia for each Pressure Limitation Manifold. The Pressure Limitation manifold has been tested under simulated clinical conditions after accelerated life and shipping tests.

Conclusion:

1. The Bebi.Plus™ Pressure Limitation Manifold is substantially equivalent in technology used to relieve excessive pressure to as Predicate K040366.
2. The Bebi.Plus™ Pressure Limitation Manifold performance (ability to relieve pressure, ability to supply fresh gas, ability to connect an oxygen sensor and ability to connect to a humidifier is substantially equivalent to Predicate K040366.
3. The Bebi.Plus™ Pressure Limitation Manifold is identical to the material of the Predicates named in Section 15 of this application and are is substantially equivalent in intended use, patient population and environment stated in Predicates K040366 and K093716.

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[1] American Association for Respiratory Care - Clinical practice Guideline Application of Continuous Positive Airway Pressure to Neonates via Nasal Prongs, Nasopharyngeal Tube, or Nasal Mask—2004 Revision & Update in RESPIRATORY CARE • SEPTEMBER 2004 VOL 49 NO 9; pages 1100 - 1108

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Mr. Thomas C. Loescher
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AUG - 1 2011

Re: K110383
Trade/Device Name: Babi*Plus™ Pressure Limitation Manifold
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuos Ventilator
Regulatory Class: II
Product Code: BZD
Dated: July 19, 2011
Received: July 20, 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

A Plus Medical

Indications for Use Statement

510(k) Number: K110383

Device Name: ***Bobs.Plus*** Pressure Limitation Manifold

Indications for Use:

Single patient use device intended for neonate, infant or child with a body mass of less than 10 Kg requiring a pressure limitation system to eliminate excessive pressure should an obstruction occur between gas supply and exhalation port during continuous gas flow therapy up to 12 liters per minute in hospital critical care unit.

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)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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