K110471

5.0. 510(k) Summary

Date: February 18, 2010

OCT - 7 2011

Owner:

A Plus Medical
5431 Avenida Encinas, STE G
Carlsbad, CA 92008-4411
Tel: + 760-930-4025
Fax: + 760-930-0040

Owner/Operator Number:

10023166

Official Contact:

Thomas C. Loescher
Tel: + 760-930-4025
Fax: + 760-930-0040

Trade Names:

***Babi*Plus™** Infant Nasal Cannula System

Common/Usual Name:

Nasal Cannula, Infant Nasal Cannula

Classification Name:

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

Device:

The ***Babi*Plus*** Nasal Cannula

Predicate Devices:

Number: K093716
Product Name: ***Babi*Plus™** Infant Nasal Cannula System
Manufacturer: A Plus Medical
Product Codes: C100 & C102

Device Description:

Single patient use nasal cannula offered in 8 different sizes which have been specifically designed for patents ≤ 10 Kg. The device includes a short length of 10 mm corrugated tubing allowing connection to a variety of devices. The device also provides a means to monitor delivered pressure at the nasal prong.

Indications for Use:

Single patient use device intended for use with neonates, infants and children under 10 Kg requiring a nasal prong interface during intermittent or continuous gas flow therapy in the hospital critical care unit.

Contraindications:

Patients not requiring a nasal prong interface during intermittent or continuous gas flow therapy.
Patients > 10 Kg.

Patient Population:

Patient population of neonate (premature infant), infant and child

Environment of Use:

Hospital Critical Care Unit

Comparative of Technological Characteristics:

The ***Babi*Plus*** Nasal Cannula is substantially equivalent in indications for use, environment of use, patient population, material and function to the identified predicate. Bench testing and dimensional analysis confirmed that the ***Babi*Plus*** Nasal Cannula and predicate device have similar performance characteristics.
Testing was performed and the below identified differences were demonstrated:

- Resistance to gas flow in the inspiratory circuit.

Gas Flow	1	2	3	4	5	6	7	8	9	10	11	12
Predicate	0	0.1	0.2	0.3	0.4	0.5	0.7	0.9	1.1	1.3	1.6	1.9
Proposed Device	<0.1	<0.1	0.1	0.2	0.2	0.3	0.5	0.6	0.8	0.9	1.1	1.3

- Resistance to gas flow in the **expiratory** circuit.

Gas Flow	1	2	3	4	5	6	7	8	9	10	11	12
Predicate	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1
Proposed Device	<0.1	<0.1	<0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.5	0.6

Conclusion:

The revised ***Babi*Plus*** Nasal Cannula is substantially equivalent to the predicate of Application K093716 because:

- Both are made from identical material.
- Both have substantially equivalent performance.
- Both have identical indications for use.
- Both are used in identical patient populations.
- Both are used in identical environments of use.

5411 Avenida Encinas, STE G
Carlsbad, CA 92008-4411
☎. +740-930-4025 Fax: +760-930-0040

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

OCT - 7 2011

Re: K110471
Trade/Device Name: Babi.Plus™ Infant Nasal Cannula System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 7, 2011
Received: September 8, 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 Kesia Alexander

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
Solutions for Respiratory Care

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **Babi**.Plus™ Infant Nasal Cannula System

Indications for Use:

Single patient use device intended for use with neonates, infants and children under 10 Kg requiring a nasal prong interface during intermittent or continuous gas flow therapy in the 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)

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

510(k) Number: k110471