K093766

## 5.0. 510(k) Summary

MAY 13 2010

**Date:** December 1, 2009

**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:**

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

**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: | K871157 |
| Product Name: | Infant Nasal CPAP Cannula |
| Manufacturer: | Hudson Oxygen Therapy Sales Company (Teleflex Medical) |
| Product Codes: | 1683, 1685, 1686, 1687, 1688, 1689, 1690, 1691, 1692, 1693, 1694, 1695 |

**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. Pre-conditioned gas (heat, moisture, flow and oxygen concentration) is provided to the device's inspiratory circuit. The gas is channeled to the nasal cannula for inhalation. Expired gas is channeled away from the nasal cannula and eventually is vented to the surrounding environment. The device also includes a pressure monitoring line to monitor nasal prong (proximal airway) pressure.

### 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 and the predicate device provide flow-by gas the nasal pharynx via a cannula body and nasal prong.
- Each device has an inspiratory side (circuit), nasal cannula body, nasal prong and an expiratory side (circuit).
- Each device allows pre-conditioned gas (heat, moisture, flow and oxygen concentration) to be delivered to the inspiratory side (circuit) of the device.
- Each device has an expiratory side (circuit) that allows expired gas to be channeled away from the nasal cannula, eventually venting into the surrounding environment.
- A dimension analysis of the ***Babi*Plus*** Nasal Cannula and the predicate was performed which demonstrated substantially equivalent dimensions as well as calculated dead space ($V_{DS}$) within the nasal prong.
- Bench Testing of the ***Babi*Plus*** Nasal Cannula and the predicate device to determine substantial equivalency in performance included:
  - Testing of resistance to gas flow in the *inspiratory* circuit of the ***Babi*Plus*** Nasal Cannula and predicate device at gas flows of 1 to 12 LPM.
  - Testing of resistance to gas flow in the *expiratory* circuit of the ***Babi*Plus*** Nasal Cannula and predicate device at gas flows of 1 to 12 LPM.
  - Testing to show the accuracy of measuring nasal prong (proximal airway) pressure at various pressures and gas flows.

### Conclusion:

- The ***Babi*Plus*** Nasal Cannula is substantially equivalent to the identified predicate.
- The ***Babi*Plus*** Nasal Cannula and the identified predicate have substantially equivalent performance.
- The ***Babi*Plus*** Nasal Cannula and the identified predicate are made from substantially equivalent material, have substantially equivalent intended uses, are used in similar patient populations and are used in the same environment.

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

MAY 13 2010

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

Re: K093716
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: April 15, 2010
Received: April 19, 2010

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:** _____ (To be assigned)

**Device Name:** ***Babi*Plus*** 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: K093716