K060497

Non-Confidential Summary of Safety and Effectiveness

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JUL 11 2006

Baby's Breath Ltd.
Ha'hadas St., Bldg. # 5
North Industrial Area
Or-Akiva, 30600 ISRAEL

Tel – 011-972-4-6262551
Fax – 011-972-4-6262552

Official Contact -- Gilad Golan – Managing Director

Proprietary or Trade Name -- BabyAir™

Common/Usual Name -- Nebulizer

Classification Name -- Nebulizer (direct patient interface)

Device -- BabyAir™

Predicate Devices -- Cardinal – Misty Max 10 – K023602

Device Description --

The BabyAir™ is comprised of:

- Transparent Hood - Covering shield draped over a plastic base.
- Nebulizer Assembly – The Nebulizer converts the liquid medication into a fine aerosol mist and directs the aerosol toward the infant efficiently and safely.
- Compressor - Not included. Any standard nebulizer compressor which has an operating flow rate range of 8 to 11 Lpm at no back pressure or has a pressure of 3 bar under a no flow conditions, may be used.

Indications for Use -- The BabyAir™ is a pneumatic nebulizer, UDN, with a hood, which nebulizes specific drugs for inhalation by a patient. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a nebulizer. This product is a single patient, multi- use, non-sterile prescriptive device

Patient Population -- For use with infants

Environment of Use -- Hospital and homecare

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Contraindications -- None

Comparative Particle Size testing --

Comparative Particle Size testing via a Cascade Impactor demonstrated that the MMAD and GSD are substantially equivalent for the BabyAir™ and the predicate.

Substantial Equivalence –

The BabyAir™ based upon a comparison to the predicate is viewed as substantially equivalent.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2006

Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court # 102
Bonita Springs, Florida 34134-2015

Re: K060497
Trade/Device Name: BabyAir™
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 1, 2006
Received: July 3, 2006

Dear Mr. Dryden:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, ~~Ph.D.~~
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

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

Device Name: BabyAir™

Indications for Use: The BabyAir™ is a pneumatic nebulizer, UDN, with a hood, which nebulizes specific drugs for inhalation by a patient. The patient population includes infants. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a nebulizer. This product is a single patient, multi- use, non-sterile prescriptive device. It is intended to be used in either a hospital or homecare environment.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** __ (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)

Anne Sullivan

n Sign-Off)
ion of Anesthesiology, General Hospital,
ion Control, Dental Devices
) Number: K060497