MAR - 6 2008



K072163

**510(k) Summary**
**for the 3A Healthcare nebulizers:**
**Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb**

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

## 1. General Information

Submitter:

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Email: gbonapace@alice.it

Summary Preparation Date: July 24, 2007

## 2. Names

Device Name: The families of Happyneb II, Happyneb III, Speedy, Nebby Plus and Myneb

Classification Name:

Nebulizer
Regulation number: 868.5630
Product Code: CAF

**3. Predicate Devices**

The 3A Health Care nebulizers Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb, with their own nebulizers, Fasterjet and Nebjet, are substantially equivalent to a combination of the following devices:

- ✓ Healthdyne, Inc - NEBULIZER SYSTEM - K922623
- ✓ Invacare - PRO, COMPACT and PORTABLE DESKTOP - K042483
- ✓ Salter Labs - Salter Aire Compressor - K992285
- ✓ Medical Industries Sport-Neb (K964078)

for compressors, and

- ✓ Salter Labs 8900 nebulizer - K870027
- ✓ Medic-Aid Sidestream Nebulizer - K991725
- ✓ Pari LC STAR nebulizer - K963924

for nebulizers.

**4. Device Description**

The family of 3A Health Care nebulizers include 5 different devices; 4 are AC powered devices (Happyneb II, Happyneb III, Speedy, Nebby Plus) and one model (Myneb) with a DC motor, a rechargeable battery pack and an external charger/power supplier.

The 4 AC compressors (Happyneb II, Happyneb III, Speedy, and Nebby Plus) have different plastic housings. There are three different types of electrical motors for AC models and one type for the DC model (Myneb). The 5 models of compressors are designed to use two nebulizers, the Fasterjet and Nebjet.

**5. Indications for Use**

The intended use of the Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb is to spray liquids in aerosol form into gases that are delivered directly to adult or pediatric patients who have been prescribed inhalation therapy or medication. Each of these nebulizers must be used exclusively with their own nebulizer and mouthpiece.

The nebulizers Happyneb II, Happyneb III, Speedy, and the Nebby Plus are intended to be used primarily by patients in the home care market, although they may also be used by trained hospital staff personnel as well. The Myneb model is intended to be used only in home health care.

The Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb are intended for multiple use, are non-sterile and for use with pharmaceutical products which are under physician prescription.

**6. Performance Data**

The non clinical performance bench tests performed by 3A Health Care Srl, have been executed as requested in "Reviewer guidance for nebulizers, metered dose inhalers, spacers and actuators" issued in October 1993, and demonstrate that 3A Health Care nebulizers have the same effectiveness as their predicate devices because they have equivalent performance parameters (MMAD, GSD, FPF and PFD). Therefore, clinical data are not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2008

3A Health Care S.r.l.
C/O Ms. Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Incorporated
5 Timber Lane
North Reading, Massachusetts 01864

Re: K072163
Trade/Device Name: Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: January 23, 2008
Received: January 28, 2008

Dear Ms. O'Connell:

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.

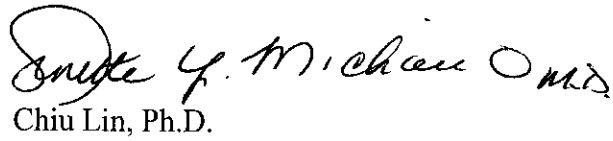
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

# Indications for Use

510(k) Number (if known): _____

**Device Name**: Happyneb II, Happyneb III, Speedy, Nebby Plus and the Myneb

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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