

K042546

JAN - 3 2005

Attachment I

## 510(k) Summary

December 21, 2004

**Submitter: InfaMed Ltd**  
**173 Mounts Bay Road**  
**Level One**  
**Perth, WA Australia 6000**  
**Phone: +61 (08) 9321 2712**

**Contact: Dennis Thiele**

### **510(k) Numbers and Product Codes of equivalent devices:**

Respironics, Inc; Optichamber®

510(k) Number: # K962822

Product Code: 73 CAF

CFR Section: 868.5630

### **Indications for Use and Intended Population**

Funhaler® is intended for use primarily in the pediatric population. Pediatric subgroups may vary, however Funhaler® is suitable to all subgroups with the exception of newborns and infants younger than 18 months. Funhaler® is used in combination with a Metered Dose Inhaler for respiratory drug delivery.

Funhaler® is primarily intended for use in the pediatric population in conjunction with prescribed Metered Dose Inhalers for their respective approved uses in accordance with physician instructions. Funhaler® is for prescription use only.

Funhaler® is only indicated for use with Metered Dose Inhalers. Other products such as Nebulizers and Actuators are not suitable for use with Funhaler®.

Funhaler® is intended to improve compliance with pediatric patients in the use of MDI's, by providing audible and visual feedback to the patient indicating the proper use of the MDI and resultant medication delivery to the patient.

### **Device Description**

The Funhaler® is basically a Spacer, similar in function and construction to commonly used Spacers such as the predicate device (Optichamber®, Respironics, Inc; K962822) and others, such as CT Spacer (K010680). The device consists of a Mouthpiece, cylindrical Spacer, tapered on each end and a molded connector compatible with approved Metered Dose Inhalers.

The Funhaler® differs from predicate device in a number of ways;

1. Funhaler® is provided with a breathing Mask in addition to the Mouthpiece. The breathing mask fits over the face (mouth and nose) to assure the full inhalation of the drug from the MDI in pediatric patients. Older (larger) patients may use the Mouthpiece in lieu of the Mask.

2. Funhaler® incorporates a Whistle to provide audible feedback when the Spacer is used properly with the MDI, aiding in compliance with children.
3. Funhaler® incorporates a Spinner Disk, having a Mylar sticker, which spins and provides visual feedback (by spinning) when the Spacer is used properly with the MDI, also aiding in compliance with children.

The Funhaler® works in conjunction with virtually all standard, approved, Metered Dose Inhalers and has been tested for particle size, distribution and drug delivery with a variety of MDI's and drugs in accordance with FDA Guidance for these devices.

Performance of Funhaler® with respect to particle size distribution has been confirmed to be better than or equal to the predicate device. Limited clinical testing has demonstrated improved compliance with children using the Funhaler® when compared to the predicate device.

### **Performance Standards**

The Funhaler® meets or exceeds the following Performance Standards:

- 21CFR820 Quality System Regulation
- ISO 10993-10; Biological Evaluation of Medical Devices; Tests for irritation and sensitization
- ISO 10993-5; Biological Evaluation of Medical Devices; Tests for Cytotoxicity (MEM)
- ISO 13485 – Quality Systems, Medical Devices
- EN 14971 – Risk Analysis
- FDA Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers, and Actuators; October 1, 1993
- 16CFR 1500:1501- Consumer Product Safety, as applicable for products intended for use with children.
- 21CFR801 – Labeling
- FDA division of Bioequivalence Guidance for the In-Vitro Portion of Bioequivalence requirements for Metaproterenol Sulfate and Albuterol Inhalation Aerosols (Metered Dose Inhalers)
- Guidance for Industry and FDA Staff-Premarket Assessment of Pediatric Medical Devices; May 2004

### **Conclusion**

There are more similarities than differences between the predicate device and the Funhaler®. Both the Funhaler® and predicate device have a similar intended use, theory of operation, materials and construction. When used in accordance with the Directions For Use, Funhaler® is safe and effective, as indicated, for its intended use.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

InfaMed Limited  
C/O Mr. John Greenbaum  
Consultant  
Generic Devices Consulting, Incorporated  
20310 SW 48<sup>th</sup> Street  
Ft. Lauderdale, Florida 33332

Re: K042546  
Trade/Device Name: Funhaler  
Regulation Number: 21 CFR 868.5630  
Regulation Name: Nebulizer  
Regulatory Class: II  
Product Code: CAF  
Dated: November 30, 2004  
Received: December 1, 2004

Dear Mr. Greenbaum:

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.

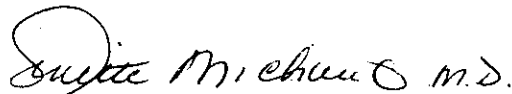
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



Chiu Lin, Ph.D.

FOR DR. CHIU LIN

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): K042546

Device Name: Funhaler

Indications for Use:

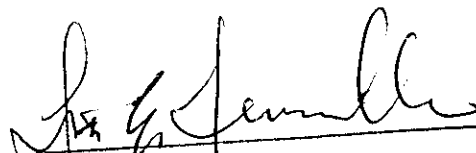
**Funhaler is intended for use primarily in the pediatric population. Funhaler is used in combination with a Metered Dose Inhaler for respiratory drug delivery.**

Prescription Use X  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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