Section 5

510(K) SUMMARY

AUG - 9 2011

Prepared: January 25, 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K110293.

1. **Submitter's Identification:**

Respironics New Jersey, Inc.
5 Wood Hollow Road
Parsippany, New Jersey
07054
Phone: 973-581-6008
Fax: 973-599-5650
Contact Name: Lauren Ziegler
e-mail: lauren.ziegler@philips.com

Establishment Registration Number: 2243193

Official Correspondent:

Lauren Ziegler
Director, QA, RA, and Clinical Affairs
5 Wood Hollow Road
Parsippany, New Jersey
07054
Phone: 973-581-6008
Fax: 973-599-5650
e-mail: Lauren.ziegler@philips.com

2. **Name of the Device:**

OptiChamber Diamond Valved Holding Chamber.
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Valved Holding Chambers, 21 CFR Part 868.5630.
Device Classification Code: NVP

3. Predicate Device Information:

Identification of legally marketed device which we claim substantial equivalence to:
AeroChamber Plus Z-Stat Valved Holding Chamber
K052332
Trudell Medical International.
725 Third Street
London, Ontario
Canada, N5V 5G4

4. Device Description:

The OptiChamber Diamond Valved Holding Chamber (VHC) is a Class II device. It is intended to be used in combination with most pressurized Metered Dose Inhalers (pMDIs) to assist in respiratory drug delivery.

The OptiChamber Diamond Valved Holding Chamber is a device utilizing the same operating principles as the AeroChamber Plus Z-Stat Valved Holding Chamber (K052332). Both the AeroChamber Plus Z-Stat and the OptiChamber Diamond are available with and without mask.

The valved holding chamber (VHC) is designed to assist patients who cannot correctly coordinate actuation of the pressurized metered dose inhaler (pMDIs) with inhalation. The VHC works by 'holding' the aerosol cloud emitted from the pMDI inside the chamber so that the larger aerosol particles are removed from the aerosol cloud by impaction into the chamber walls and sedimentation under the influence of gravity.

The OptiChamber Diamond Valved Holding Chamber is made of antistatic plastic materials alleviating any need to wash prior to first use. OptiChamber Diamond is comprised of: the mouthpiece, the chamber, the adapter (end cap) with inhalation flow alert, the exhaust valve, the inhalation valve, the valve retaining ring, and the cap.

5. Intended Use:

The OptiChamber Diamond Valved Holding Chamber device is intended to be used by patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. The intended environments for use include the home, hospitals and clinics.
For Single Patient Use
Recommended Patient Population:
OptiChamber Diamond: Age 5 and up
OptiChamber Diamond with Small LiteTouch mask: 0 to 18 months

OptiChamber Diamond with Medium LiteTouch mask: 1 to 5 years
OptiChamber Diamond with Large LiteTouch mask: 5 years +

---

6. Comparison to Predicate Devices:

The OptiChamber Diamond Valve Holding Chamber and the predicate device (AeroChamber Plus Z-Stat Valved Holding Chamber (K052332)) are indicated for the same intended use and their performance characteristics are substantially equivalent. Both the AeroChamber Plus Z-Stat and the OptiChamber Diamond are available with and without mask.

The LiteTouch medium mask was approved under K100285.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

A pressurized Metered Dose Inhaler (pMDI) alone and a pMDI with the OptiChamber Diamond valved holding chamber (VHC) were tested utilizing a Next Generation Impactor (NGI) with a custom flat plate adapter and operated at 15 and 30 liters per minute (LPM). The 15 liters per minute was chosen to simulate pediatric breathing pattern and the 30 liters per minute was chosen to simulate adult breathing pattern (reference: Breathing patterns, K. Nikander, J. Denyer, Eur Respir Rev 2000; 10: 76, 576-579). The pMDI was actuated 10 times into each device. Deposition of drug on various locations of the NGI was qualified using HPLC assays.

MMAD, GSD, FPD, and FPF results were determined using CITDAS (reference: Performance Verification of Copley Inhaler Testing Data Analysis Software (CITDAS), Respiratory Drug Delivery Europe 2009 –Krebs et al.) software version 3.10. Fine particle dose (FPD) was presented as 3 categories: greater than 4.7um, less than or equal to 4.7um and less than or equal to 1.0um. Fine particle fraction (FPF) is defined as the fraction of dose entering the impactor equal to or less than 4.7um.

Three inhaler formulations (albuterol, fluticasone propionate and ipratropium bromide) were evaluated.

Definitions:

ED = Total Emitted Dose: Total amount of drug from VHC + USP Throat + NGI components + Filter

FPD = Fine Particle Dose: amount of drug entering the impactor with an aerodynamic diameter between specific limits.

FPF = Fine Particle Fraction: a fraction of dose entering the impactor with an aerodynamic diameter of ≤ 4.7um

MMAD = Mass Medium Aerodynamic Diameter: The geometric mean aerodynamic diameter. Fifty per cent of particles by weight will be smaller than the MMAD, 50% will be larger.

GSD = Geometric Standard Deviation: A measure of dispersion in a lognormal distribution always greater than or equal to 1.0.

8. Discussion of Clinical Tests Performed:

Not Applicable.

9. Conclusions:

We have demonstrated that the OptiChamber Diamond Valved Holding Chamber is substantially equivalent to the predicate device, the AeroChamber Plus Z-stat Valved Holding Chamber, through in Vitro Testing. The two devices are also substantially equivalent in terms of their features, operating principle, and indications for use.

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

Ms. Lauren Ziegler
Director, Quality Assurance, Regulatory Affairs
Respironics New Jersey, Incorporated
5 Wood Hollow Road
Parsippany, New Jersey 07054

AUG - 9 2011

Re: K110293
Trade/Device Name: OptiChamber Diamond Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: July 21, 2011
Received: July 25, 2011

Dear Ms. Ziegler:

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

Indications for Use

510(k) Number (if known): K110293

Device Name: OptiChamber Diamond Valved Holding Chamber

Indications for Use:

The OptiChamber Diamond Valved Holding Chamber device is intended to be used by patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. The intended environments for use include the home, hospitals and clinics.

For Single Patient Use
Recommended Patient Population:

OptiChamber Diamond: Age 5 and up
OptiChamber Diamond with Small LiteTouch mask: 0 to 18 months
OptiChamber Diamond with Medium LiteTouch mask: 1 to 5 years
OptiChamber Diamond with Large LiteTouch mask: 5 years +

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 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: _____