Section 5

JUN 2 9 2010

510(K) SUMMARY

Prepared: October 15, 2009

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: K100285

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@respironics.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@respironics.com

2. **Name of the Device:**

LiteTouch mask
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Mask, 21 CFR Part 868.5630.
Device Classification: CAF

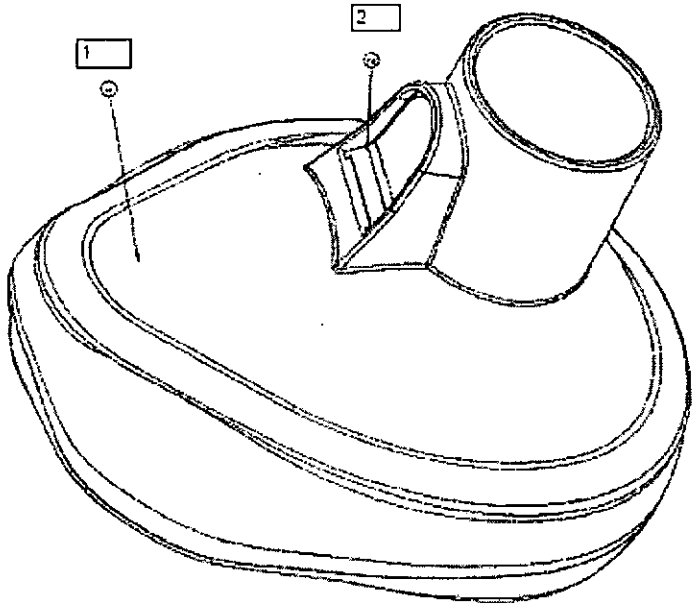
3. Predicate Device Information:

Identification of legally marketed device which we claim substantial equivalence to:
AeroChamber Max Valved Holding Chamber Small and Medium Mask
K032972
AeroChamber Plus Valved Holding Chamber (K992917)
Trudell Medical International.
725 Third Street
London, Ontario
Canada, N5V 5G4

4. Device Description:

The LiteTouch mask is a Class II device. It is a mask for use with Respironics' OptiChamber Valved Holding Chamber (K962822).

The LiteTouch mask is a mask that utilizes the same operating principles as the AeroChamber Max Valved Holding Chamber Small and Medium Mask (K032972). The difference between the LiteTouch mask and the AeroChamber Max Valved Holding Chamber Small and Medium Mask is that, the LiteTouch mask does not come assembled to the chamber and the exhalation valve is located in different positions and is not of the same shape. (See picture below).



1 Face Plate Cushion Assembly
2 Flap Valve

The objective in using a mask is to have patients who are unable to use a spacer mouthpiece or have difficulty with hand-breath coordination get their medication through normal breathing pattern.

To use the LiteTouch mask, the user needs to unpack the mask and attach it to the mouthpiece end of the spacer. The MDI (including the actuator) is inserted into the opening in the MDI adaptor at the distal end of the spacer. The MDI and the spacer combination should be shaken vigorously just prior to inhalation. The patient should exhale normally through the mask. The valve from the mask prevents room air from entering the mask as the patient inhales. The valve's opening and closing movement also indicates that there is an effective mask/face seal; that the patient is breathing and how fast the patient is breathing.

The LiteTouch mask comprises of a Flap Valve and a Cushion plate.

5. Intended Use:

The LiteTouch medium mask for ages 1-5 is to be used with OptiChamber Advantage Valved Holding Chambers. The mask is intended to be used to help administer aerosolized medication from most pressurized metered dose inhalers used with valved holding chambers as prescribed by a physician or health care professional. The intended environments for use include homes, hospitals, and clinics.

6. Comparison to Predicate Devices:

The subject LiteTouch mask and the predicate device (AeroChamber Max Valved Holding Chamber Small and Medium Mask (K032972) are indicated for the same intended use. The difference between the LiteTouch mask and the AeroChamber Max Valved Holding Chamber Small and Medium Mask is that, the LiteTouch mask does not come assembled to the chamber and the exhalation valve is located in different locations and is not of the same shape.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The LiteTouch medium mask was tested while attached to the OptiChamber Valved Holding Chamber in comparison with the OptiChamber Valved Holding Chamber (K962822) for Fine particle Dose (Reference table 1 below).

FINE PARTICLE DOSE COMPARISON (0.4-4.7μg)

	Drugs		
Devices	Ventolin	Flovent	Atrovent
OptiChamber with LiteTouch	21.1	18.5	3.7
OptiChamber without LiteTouch	29.5	27.1	5.4

FINE PARTICLE DOSE PERCENTAGE (Drug mass recovered)
OCA with LiteTouch vs OCA without LiteTouch (%)

	Drugs		
Devices	Ventolin	Flovent	Atrovent
(OptiChamber with LiteTouch ÷ Optichamber without LiteTouch) *100	71.5	68.3	68.5

Table 1

The LiteTouch medium mask was also tested during inhalation in comparison with other facemasks to determine leaks (Reference table 2 below).

% LEAK TEST RESULTS WITH TILT ANGLES AND APPLIED FORCES

Devices

rce	Litetouch (softSeal) mask					AeroChamber Plus mask					OptiChamber mask (Pediatric)					AeroChamber Max mask					PocketChamber mask (Panda)				
	-5°	**-10°**	**0°**	**5°**	**10°**	**-5°**	**-10°**	**0°**	**5°**	**10°**	**-5°**	**-10°**	**0°**	**5°**	**10°**	**-5°**	**-10°**	**0°**	**5°**	**10°**	**-5°**	**-10°**	**0°**	**5°**	**10°**
lb	13.8	79.6	2.73	23	81.4	75.7	79	74.2	89.5	97.6	65.2	74.2	58	78.1	96.3	69.6	72.2	73.6	93.3	97.7	98.8	97.7	98	99.4	100
lb	6.13	10.5	2.5	21	71.7	73.8	76.1	70.9	86.4	94.6	61.5	72.7	49.8	72.1	96	57.5	73.8	68.2	84.6	95.9	89.4	83.8	71.6	97.6	99.4
lb	2.9	7.1	1.5	19	46.5	67.5	76.6	69	82.4	91.4	63	66.8	48.9	67.8	95.2	57.4	74.3	59.3	74.5	74.9	75	78.6	59	93.2	92.1

Table 2

Force:

- 1lb, 2lb, 4lb are forces applied to the facemasks while on the face to create a seal.

Angle (0° is the baseline)

- -5° is the angle of the chin tilting 5° upward from the baseline creating a gap between the mask and the nose bridge.
- -10° is the angle of the chin tilting 10° upward from the baseline creating a gap between the mask and the nose bridge.
- 0° is the baseline
- 5° is the angle of the chin tilting 5° downward from the baseline creating a gap between the mask and the chin.
- 10° is the angle of the chin tilting 10° downward from the baseline creating a gap between the mask and the chin.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the LiteTouch Mask is as safe and effective as a predicate device, the AeroChamber Max Valved Holding Chamber Small and Medium mask, presently on the market, based on substantially equivalent of effectiveness of the seal to the face, Dead space volume, and resistance to inhalation testing. The performance of the LiteTouch before and after washing is also substantially equivalent. The two devices are also substantially equivalent in terms of their 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

Respironics New Jersey, Incorporated
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

JUN 29 2010

Re: K100285
Trade/Device Name: LiteTouch Mask
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 10, 2010
Received: June 14, 2010

Dear Mr. Devine:

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): K100285

Device Name: LiteTouch mask

Indications for Use:

The LiteTouch medium mask for ages 1-5 is to be used with OptiChamber Advantage Valved Holding Chambers. The mask is intended to be used to help administer aerosolized medication from most pressurized metered dose inhalers used with valved holding chambers as prescribed by a physician or health care professional. The intended environments for use include homes, hospitals, and clinics.

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: K100285