DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 15, 2014

Trudell Medical International
Mr. Darryl Fischer
Associate Director, Global Regulatory Affairs
725 Third Street
London, Ontario N5V 5G4
CANADA

Re: K140919
Trade/Device Name: RespiConnect™ Adapter
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: II
Product Code: CAF
Dated: July 14, 2014
Received: July 16, 2014

Dear Mr. Fischer:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K140919

Device Name:

Indications for Use:

The RespiConnect Adapter is designed to be used with **RESPIMAT**™ SOFT MIST INHALERS to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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* Trade marks and registered trademarks of Trudell Medical International

Section 5 – 510(k) Summary

Prepared: 21 March 2014 / Amended 15 Aug 2014

510(k) Owner Trudell Medical International
725 Third Street
London, Ontario N5V 5G4
CANADA
Contact Person Darryl Fischer
Associate Director, Global Regulatory Affairs
Phone 1-519-455-7060 ext 2140
Fax 1-519-455-6329
e-mail dfischer@trudellmed.com

Device Name
Proprietary RespiConnect Adapter
Common/Classification Accessory to a nebulizer

Product Code CAF

Classification Regulation 868.5630

Predicate Device(s) ***510(k) Number***	***Trade/Model Name***	***Manufacturer***
K926301	Ace Cloud Enhancer	DHD Diemolding, Healthcare Division

Device Description

The RespiConnect Adapter is a single-patient use device intended to provide a self-sealing access port in a ventilator circuit to facilitate the administration of ***Respimat***™ Soft Mist inhaler medication to mechanically ventilated patients.

Intended Use

The RespiConnect Adapter is designed to be used with ***RESPIMAT***™ SOFT MIST INHALERS to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.
The intended use does not differ significantly from that of the predicate device detailed below. The predicate device below is designed to assist with the delivery of aerosolized medications from metered dose inhaler canisters to a mechanically ventilated patient.

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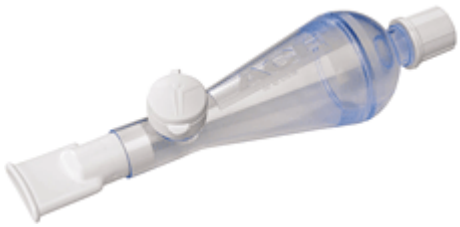
Ace Aerosol Cloud Enhancer, K926301 • Manufactured from plastic • 22mm OD and ID fittings to accommodate 22 mm breathing circuit connections • Used to administer aerosolized medication to a mechanically ventilated patient	

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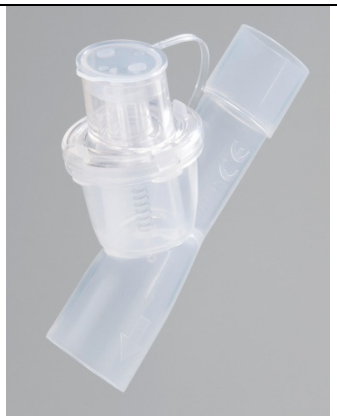
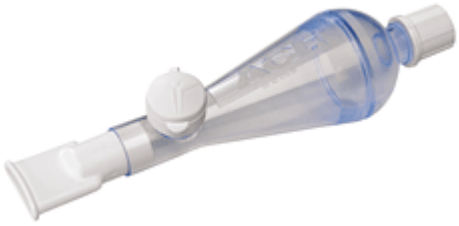
Technological Characteristic Comparison to Predicate Device

The table below presents some of the common device characteristics exhibited by the Class II device and the predicate device.

Common Device Characteristics		
Characteristic	 **RespiConnect Adapter for Respimat™**	 **ACE Aerosol Cloud Enhancer K926301**
Single Patient Use	**Yes**	**Yes**
For use in a ventilator circuit	**Yes**	**Yes**
Delivery of aerosol medication	**Yes**	**Yes**
Built in actuator	**No**	**Yes**
Sold non-sterile	**Yes**	**Yes**
22mm ISO fittings	**Yes**	**Yes**
Device Classification:	**Class II – Accessory to a nebulizer**	**Class II – Accessory to a nebulizer**

Relevant differences in the operating principles of the Adapter for Respimat™ and the predicate device;

- RespiConnect Adapter is used only with the Respimat™ Soft Mist Inhaler (SMI) device.
- RespiConnect Adapter has a self-sealing port to maintain circuit integrity once the Respimat™ device is removed. The ACE device must be capped to prevent circuit leakage if it remains in the circuit after use.
- RespiConnect Adapter remains in the circuit once installed, and is discarded with the circuit upon circuit change. The ACE device is not recommended to remain in the circuit once in place, and may be removed after each use.
- RespiConnect Adapter has a molded arrow to indicate direction of air flow. The ACE device is not labeled with the direction of air flow.

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- RespiConnect Adapter is not patient-orientation sensitive while medication is being delivered. The ACE device and pMDI is patient-orientation sensitive during aerosol delivery, as the pMDI must be oriented in the upright position during firing to ensure the labeled dosage of drug is properly delivered.

Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (leakage) of the RespiConnect Adapter device. The results (in Section 11, Attachment 4) demonstrate that the RespiConnect Adapter device performs satisfactorily, and does not raise any new safety or efficacy related issues.

There are no direct patient contacting components of the RespiConnect Adapter device. However, the materials of construction were tested for biocompatibility and do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of the RespiConnect Adapter device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
    - Cytotoxicity – according to ISO 10993-5
    - Sensitization – according to ISO 10993-10
    - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Aerosol testing was performed to characterize cascade impactor performance data for total delivered dose, respirable fraction and respirable particle mass using the subject device. Review of the performance results indicate no new safety or efficacy issues were raised as a result of the testing. Expected performance results have been added to the instructions for use for the RespiConnect Adapter for user reference.

Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The RespiConnect Adapter device has been compared against a currently marketed (predicate) device for the determination of substantial equivalency. The RespiConnect Adapter device and the predicate device share:

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- common indications for use for mechanically ventilated patients
- usage environments
- both devices are single patient use
- both devices are sold non-sterile

The RespiConnect Adapter device raises no new issues regarding safety or efficacy.