K123614

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Section 5 – 510(k) Summary

Prepared: 20 November 2012

510(k) Owner Trudell Medical International
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CANADA

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Device Name

Proprietary ***Solarys**** Ventilator Aerosol Delivery System
Common/Classification Nebulizer, Direct Patient Interface

Product Code CAF

Classification Regulation 868.5630

Predicate Device

510(k) Number	Trade/Model Name(s)	Manufacturer
K070642	Aeroneb Professional Nebulizer System - Aeroneb Solo	Aerogen Limited

Device Description

The ***Solarys**** Ventilator Aerosol Delivery System (AS)

The ***Solarys**** Ventilator Aerosol Delivery System (AS) is a single-use (disposable) continuous nebulizer system designed for use with mechanically ventilated patients to aerosolize physician-prescribed medications for inhalation.

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Intended Use

The ***Solarys**** Ventilator Aerosol Delivery System (AS) is a nebulizer intended to deliver prescribed aerosolized medication to mechanically ventilated pediatric and adults patients able to use an Endotracheal Tube equal to or greater than 4.5 mm in diameter. The device is designed to operate in-line with ventilator circuits and mechanical ventilators in acute and sub-acute care environments.

Technological Characteristic Comparison to Predicate Device(s)

Common characteristics to both the ***Solarys**** AS and the predicate device ;
- operate primarily by atomizing bulk liquid containing medication into an aerosol form that can be inhaled
- both have a reservoir that is part of the medication delivery system for extended treatments
- both devices allow for refilling during extended treatments, without having to break the patient circuit

Relevant differences in operating principles of the ***Solarys**** AS and the predicate device;
- the ***Solarys**** AS is a pneumatically driven nebulizer, whereas the Aerogen Solo system is a vibrating mesh nebulizer that is electrically driven.
- No cleaning of the ***Solarys**** AS system is required to maintain nebulizer performance (remains in the patient circuit for the duration of circuit life). The predicate device requires cleaning to prevent clogging of the vibrating mesh to maintain its performance with many formulations.

Non-Clinical Test Summary

Evaluation of the ***Solarys**** AS and the predicate device was performed in accordance with the relevant sections of the CDRH Guidance Document *"Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH/ODE/DCRD/ADDB -1993).*

- Aerosol characterization testing for the ***Solarys**** AS and the predicate device has been conducted with 3 commonly prescribed drugs using the cascade impactor method. The total mass of each drug emitted was determined by simulating normal device usage in a ventilator circuit and demonstrates that the performance of the ***Solarys**** AS raises no new issues of safety or effectiveness from the legally marketed predicate device. Constant sampling through an

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impactor at a fixed flow rate does not provide an accurate indication of the amount of medication potentially available in a clinically relevant situation, so in order to obtain a representative measurement of total emitted mass (TEM), a simulated adult mechanically ventilated patient was used to assess the mass of medication available at the exit of a 7.0 mm I.D. ETT. The aerosolized medication exiting the ETT was collected directly onto a polypropylene microfiber filter, connected to an adult mechanical test lung that was used as the patient model.

- Biocompatibility testing was conducted on the Solarys* AS device according to ISO 10993-1
- Mechanical safety testing consisted of the following;
  - Simulated use
  - Maximum pressure testing
  - Environmental limit testing (operating limits and environmental storage and transportation testing)
  - Drop testing
  - Connection leakage
  - Strain relief fatigue and tensile testing

The aerosol characterization specifications below have been defined based on statistical analysis (95% confidence interval) of the observed data collected using cascade impactor methodology.

Particle Size Characterization				
			Combivent	
	Albuterol	Ratio-Ipratropium	Albuterol	Ipratropium Bromide
Filter / Breathing Simulator Data				
Total Delivered Dose ex ETT (µg)	724	296	1593	390
NGI Data				
Particle Fraction Greater Than 8.64µm (%)	24.3	21.6	26.3	26.5
Particle Fraction Between 0.98 – 8.64 µm (%)	70.2	73.4	68.2	68.0
Particle Fraction Less Than 0.98 µm (%)	5.5	5.0	5.5	5.5
MMAD (µm)	4.3	4.0	4.6	4.7
GSD	2.8	2.8	2.7	2.8

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Clinical Performance Summary

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

Conclusions from Testing

The ***Solarys**** AS has been evaluated against a currently marketed (predicate) device for the determination of substantial equivalency. The ***Solarys**** AS and the predicate device share common indications for use and usage environments. The devices are both single patient use, non-sterile, disposable and are available by prescription.

Performance data, gathered in accordance with *"Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH/ODE/DCRD/ADDB -1993)*, demonstrate that the ***Solarys**** AS raises no new issues of safety or effectiveness from the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Mr. Darryl Fischer, CQM
Associate Director, Global Regulatory Affairs
Trudell Medical International
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Re: K123614
Trade/Device Name: Solarys* Ventilator Aberosol Delivery System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 21, 2012
Received: December 26, 2012

Dear 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 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,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Indications for Use

510(k) Number: K123614

Device Name: ***Solarys**** Ventilator Aerosol Delivery System

Indications for Use:

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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)

Albert E. Moyal -S for LS

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

510(k) Number: _____

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