K111246

Armstrong Medical	Section 5 510(K) Summary Spirale Drug Delivery System

5.1 Applicants Name and Address

AUG 10 2012

Armstrong Medical Ltd
Wattstown Business Park
Newbridge Road
Coleraine
Northern Ireland

5.2 Applicants Contact Details

Ian Stewart
Development and Quality Systems Engineer.

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5.3 Date Summary was prepared

April 2011, revised July 2012.

5.4 Device Name

Spirale DDS

5.5 Classification.

Class II
FDA Classification 21CFR 868.5630
Product Code: CAF

5.6 Legally marketed device to which Equivalence is claimed

Aerovent collapsible Holding Chamber, product code: 85951. Manufactured by: MONAGHAN MEDICAL CORP, 5 latour ave., suite1600, p.o.box 2805, Plattsburgh, NY 12901 and distributed by Trudell Medical 725 Third Street, London, Ontario, Canada, N5V 5G4

5.7 Description of the Device.

The purpose of a drug nebuliser device is to facilitate the nebulisation of respiratory drugs and non-pharmacological (placebo) solutions and to allow the transfer of these preparations to patients via the drug nebuliser. Usage is predominantly for patients receiving treatment in anaesthetic and intensive care settings within hospital theatres, intensive care units, and accident and emergency departments.

The aim of treatment with a nebuliser is to deliver a therapeutic dose of the drug as an aerosol in the form of respirable particles and to obtain a response from the interaction between drug molecules and lung cell receptors, within a fairly short period of time, usually 5 to 10 minutes. Nebulisers are useful when large doses of inhaled drugs are needed, when patients are too ill or otherwise unable to use hand-held inhalers, and when drugs are not available in hand-held inhalers.

5.8 Intended Use

Spirale DDS is a collapsible volumising chamber for the delivery of aerosolized micro drug particles from an MDI (metered dose inhaler) canister into a respiratory breathing circuit during anaesthesia or intensive care ventilation in the spontaneously-breathing or ventilated patient.

5.9 Substantial Equivalence

We are claiming substantial equivalence to the Trudell Aerovent collapsible Holding Chamber (Monaghan Medical). Both products are connected onto the inspiratory limb of a ventilator circuit; both can be collapsed when not in use.

Key elements are the same such as jet orifice diameter, total volume collapsed and expanded, distance of nozzle travel canister depression and manufacturing material.

No adverse advent has been reported on either type of product; therefore both products are safe and effective for use during treatment of a patient.

5.10 Materials used in

1. K-Resin® Styrene-Butadiene Copolymers.
2. 40646C TRANSPARENT PURPLE MASTER.
3. Metallocene polyethylene reinforced with a polypropylene helix.
4. LOCTITE® 3106™.
5. 7132M 1/32" white medical grade foam tape.

In summary, Armstrong Medical has demonstrated that the Spirale Drug delivery system is substanically equivalent to the Trudell Aerovent collapsible Holding Chamber. It has been proven that the products are safe and effective while in use.

Spirale must be airtight to ensure no leakage of respiratory drugs and non-pharmacological solutions; the foam disk feature comes into use when the product is collapsed this design feature will ensure no medical gases are leaking from the circuit when the Spirale is attached to the circuit. Product must also expand and collapse during use without any difficulty. These features are 100% examined during assembly of the product.

5.11 Non-Clinical Tests.

They following tests were carried out on the Spirale DDS before approval to manufacture and market the devices;

1. Working Environment: Device must withstand insertion and removal forces associated with normal use
2. Handling and Transportation Conditions: Must withstand temperature range of –40°C to + 50°C
3. Physical Requirements: Jet orifice and canister interface to be designed to be geometrically equivalent to Aerovent chamber from Trudell Medical to ensure safety and effectiveness.
4. Physical Requirements: Spirale connectors and supplied adaptors to be compatible with existing Armstrong Medical ventilator circuit connections.
5. Product Testing: Glued seams to be leak free at pressures up to 60cmH_2O in both the open and closed/locked positions to withstand normal operating conditions.
6. Product Testing: Collapsible.
7. Lock and unlock positions easily identifiable, easily released from locked.

All tests were carried out and passed, therefore product was approved for manufacture and marketing. Spirale DDS is compatible with circuits marketed under the 510(k) reference numbers listed below:

K922789	KING SYSTEMS CORP. UNIVERSAL F BREATHING CIRCUIT
K920885	VITAL SIGNS, INC. VENTILATOR CIRCUIT
K812774	HUDSON OXYGEN THERAPY SALES CO. VENTILATOR CIRCUIT

As the predicate devices have been on the market for many years with no reportable incidences in this time, we can assumed from the bench tests carried out to evaluate the performance of the device under actual clinical working conditions, that the Spirale DDS will perform as safe and effective as the predicate.

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

AUG–1-0–2012

Mr. Ian Stewart
Development and Quality Systems Engineer
Armstrong Medical Limited
Wattstown Business Park, Newbridge Road
Coleraine
Northern Ireland BT52 1BS

Re: K111246
Trade/Device Name: Spirale DDS (Drug Delivery System)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 24, 2012
Received: July 27, 2012

Dear Mr. Stewart:

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,

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

Armstrong Medical	Section 4 510(K) Indications For Use Statement Spirale Drug Delivery System

Indications for Use Form

510(k) Number (if known): K111246

Device Name: Spirale DDS (Drug Delivery System)

Indications for Use:

Spirale DDS is a collapsible volumising chamber for the delivery of aerosolized micro drug particles from an MDI (metered dose inhaler) canister into a respiratory breathing circuit during anaesthesia or intensive care ventilation in the spontaneously-breathing or ventilated patient.

Prescription Use ✓ (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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

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

510(k) Number: K111246