K101953

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510(k) Summary
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24-Dec-10

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Official Contact: Tish Anger - VP Quality & Regulatory Assurance

Proprietary or Trade Name: SMDIA-1000

Common/Usual Name: Accessory to a nebulizer

Classification Name/Code: CAF – nebulizer
CFR 868.5630

Device: Southmedic SMDIA 1000

Predicate Devices: Instrumentation Industries
K991355 - RTC-22-D
K091111 - RTC-24V

Device Description:
The Southmedic SMDIA-1000 is an adaptor which acts as an actuator for intermittent delivery of prescribed aerosol medications dispensed by meter dose inhalers (MDI). The SMDIA-1000 is connected to ventilator tubing and the MDI connected when drug delivery into the circuit is required. The SMDIA-1000 adaptor may also be connected to the endotracheal tube.

Indications for Use:
The SMDIA-1000 MDI adaptor is intended to be used with an MDI for intermittent delivery of prescribed aerosol medications dispensed in MDI's. They are intended for use only when connected to ventilator tubing or tracheal tubes.

Environment of Use:
The expected clinical environment is critical care and / or long or short term ventilation, which can occur in hospitals, ICU, sub-acute centers, and home settings.

Patient Population:
The SMDIA-1000 is intended to be prescribed for any patient who is ventilator dependent and to whom a MDI has been prescribed.

Summary of substantial equivalence

	Southmedic SMDIA-1000	**Predicate - Instrumentation Industries K991355 - RTC-22-D & K091111 - RTC-24V**
Indications for Use	The SMDIA-1000 MDI adaptor is intended to be used with an MDI for intermittent delivery of prescribed aerosol medications dispensed in MDIs. They are intended for use only when connected to ventilator tubing or tracheal tubes.	The RTC series MDI adapters are actuators for intermittent delivery of prescribed aerosol medications dispensed in meter dose inhalers. The RTC series MDI adapters are intended for use only when connected to ventilator tubing or tracheal tubes.
Environment of use	The expected clinical environment is critical care and / or long or short term ventilation, which can occur in hospitals, ICU, sub-acute centers, and home settings.	The expected clinical environment is critical care and / or long or short term ventilation.
Patient Population	For any patient who is ventilator dependent and to whom a MDI has been prescribed.	For any patient who is ventilator dependent and to whom a MDI has been prescribed.
Prescriptive	Yes	Yes
Design		
Placed in the breathing circuit	Yes	Yes
May attach to a tracheal tube	Yes	Yes
Tee with standard 15 mm / 22 mm fittings	Yes	Yes
Fitting for adaption to MDI	Yes	Yes
Cap when not in use	Yes	Yes
Single patient use, disposable	Yes	Yes
Performance Testing		
Particle characterization via Cascade Impactor	3 samples with 3 different drugs MDI burst Same sample testing for intra-sample variability	3 drug types 1 sample each
Simulated life cycle and environmental testing	Environment, operational, drop, canister activation and connection trial testing	Not listed
ISO 10993 testing	ISO 10993 – Cytotoxicity, Irritation , Sensitization	Not specified

In summarizing the above comparative table the SMDIA-1000 is viewed as substantially equivalent to the predicate devices because:

Indications –

- Intended to be used with an MDI for intermittent delivery of prescribed aerosol medications dispensed in MDIs. They are intended for use only when connected to ventilator tubing or tracheal tubes. These indications for use are identical to the predicate - K091111 – RTC-24V

Technology –

- The tee design with a port which is capped when not in used is identical to the predicate - K091111 – RTC-24V

Materials –

- The materials in the gas or fluid pathway have been tested per ISO 10993 for Cytotoxicity, Irritation, and Sensitization

Environment of Use –

- The expected clinical environment is critical care and / or long or short term ventilation, which can occur in hospitals, ICU, sub-acute centers, and home settings in substantially equivalent to the predicate – K091111 – RTC-24V

Comparative Performance –

- Comparative Particle characterization testing via Cascade Impactor demonstrated that the performance of the proposed device and the predicate were equivalent
- Additional performance testing included Simulated life cycle, environmental, operational, drop, canister activation and connection trial testing, inter- and intra-sample testing for variability. For which the proposed device met its pass / fail criteria or was found substantially equivalent to the predicate.

Differences –

There are no significant differences between the proposed device and the predicate device.

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

Southmedic, Incorporated
C/O Mr. Paul E. Dryden
President
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

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Re: K101953
Trade/Device Name: SMDIA-1000
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 24, 2010
Received: December 27, 2010

Dear Mr. Dryden:

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

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Indications for Use Statement

510(k) Number: **K101953**

Device Name: **SMDIA – 1000**

Indications for Use:

The SMDIA-1000 MDI adaptor is intended to be used with an MDI for intermittent delivery of prescribed aerosol medications dispensed in MDIs. It is intended for use only when connected to ventilator tubing or tracheal tubes.

The SMDIA-1000 MDI adaptor is single patient use, disposable.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

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