K091111

Instrumentation Industries, Inc.
We make Respiratory Care Work!

DEC - 2 2009

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Date Prepared: April 10, 2009
Revised: November 23, 2009
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

510(k) SUMMARY
for
RTC 24-V MDI Adapter and RTC 24-V MDI Adapter Kit

Trade Name	RTC 24-V Metered Dose Inhaler Adapter RTC 24-V Metered Dose Inhaler Adapter Kit
Common Name	Actuator
Classification Name	Nebulizer
Regulation	21 CFR 868.5630
Predicate Device	Instrumentation Industries, Inc. RTC 22-D (K991355)
Device Description	The Instrumentation Industries, Inc. RTC 24-V metered dose inhaler adapter is an actuator for intermittent delivery of prescribed aerosol medication dispensed in metered dose inhalers. The RTC 24-V metered dose inhaler adapter kit is comprised of the Instrumentation Industries, Inc. components normally used by respiratory therapists to integrate our existing actuators into a ventilator circuit. The kit includes one RTC 24-V MDI adapter, one 4 inch length of 22mm ID tubing and one 15mm ID/22mm OD adapter
Intended Use of the Device RTC 24-V Metered Dose Inhaler Adapter	The Instrumentation Industries, Inc. RTC 24-V MDI Adapter is an actuator for intermittent delivery of prescribed aerosol medication dispensed in cylindrical-style metered dose inhalers. The RTC 24-V MDI Adapter is intended for use only when connected to ventilator tubing or tracheal tubes. The RTC 24-V MDI Adapter is intended to be prescribed for any patient who is ventilator-dependent and to whom a metered dose inhaler has been prescribed. The expected clinical environment for the RTC 24-V MDI Adapter is Critical Care and/or

	long term or short term ventilation. The RTC 24-V MDI Adapter is intended for single patient reuse. This device is intended for sale by or on the order of a physician.
RTC 24-V Metered Dose Inhaler Adapter Kit (To be sold as model number RTC 24-V KIT)	The Instrumentation Industries, Inc. RTC 24-V KIT includes the RTC 24-V MDI Adapter actuator for intermittent delivery of prescribed aerosol medication dispensed in cylindrical-style metered dose inhalers. The RTC 24-V KIT is intended for use only when connected to ventilator tubing or tracheal tubes. The RTC 24-V KIT is intended to be prescribed for any patient who is ventilator-dependent and to whom a metered dose inhaler has been prescribed. The expected clinical environment for the RTC 24-V KIT is Critical Care and/or long term or short term ventilation. The components of the RTC 24-V KIT consist of one RTC 24-V MDI Adapter, one four inch length of 22 mm inner-diameter tubing, and one 15 mm inner-diameter/22 mm outer-diameter adapter. The RTC 24-V KIT is intended for single patient reuse. This device is intended for sale by or on the order of a physician.
Technological Characteristics	**Similarities:** The function, inlet and outlet end dimensions, and the materials of both the RTC 22-D predicate device and the RTC 24-V are the same. Both the RTC 22-D and the RTC 24-V will accept plastic or metal tipped, cylindrically-shaped MDI canisters. All materials are latex-free. Materials – Body – Polystyrene Butadiene Cap – Thermoplastic Rubber Functional Dimensions – Inlet – 15mm I.D Outlet – 15mm I.D./22 mm O.D. Markings – Both the RTC 24-D and the RTC 22-D are marked with a molded-in arrow defining direction of flow. **Differences:** The RTC 24-V design includes a gear that is designed to mate with a limited number of brands of metered dose inhalers that have an integral dose counter. The interaction of the adapter gear and the dose counter permits accurate monitoring of the amount of doses remaining in the inhaler device. The RTC 22-D does not include a similar gear. There currently is not a kit version of the RTC 22-D. Users must purchase the MDI adapter, the tubing and the straight connector separately.

Aerosol Performance	The RTC 24-V was tested in the laboratory with the following MDI medications: - Ventolin® HFA - Atrovent® HFA - QVAR® In the tests (shown below) that were performed upon the RTC 24-V and the RTC 22-D predicate device, actual differences were not statistically significant: Particle Size (MMAD) Geometric Standard Deviation (GSD) Medication Captured on USP Throat In the tests (shown below) that were performed upon the RTC 24-V and the RTC 22-D predicate device, actual differences were statistically significant, with the RTC 24-V out-performing the RTC 22-D. Total Dose Delivered Respirable Fraction Total Respirable Dose Delivered Medication Retained in Device
Conclusion:	In laboratory testing the RTC 24-V is substantially equivalent to the RTC 22-D predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Doris Walter
Regulatory Affairs/Quality Assurance Manager
Instrumentation Industries, Incorporated
2990 Industrial Boulevard
Bethel Park, Pennsylvania 15102

DEC - 2 2009

Re: K091111
Trade/Device Name: RTC 24-V Metered Dose Inhaler Adapter and RTC 24-V Metered Dose Inhaler Adapter Kit
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: November 23, 2009
Received: November 25, 2009

Dear Ms. Walter:

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.

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

Susan Runner, D.D.S., M.A.
Acting Division 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):

K091111

Device Name:

RTC 24-V Metered Dose Inhaler Adapter

Statement of Indications for Use:

RTC 24-V Metered Dose Inhaler Adapter

The Instrumentation Industries, Inc. RTC 24-V MDI Adapter is an actuator for intermittent delivery of prescribed aerosol medication dispensed in cylindrical-style metered dose inhalers. The RTC 24-V MDI Adapter is intended for use only when connected to ventilator tubing or tracheal tubes.

The RTC 24-V MDI Adapter is intended to be prescribed for any patient who is ventilator-dependent and to whom a metered dose inhaler has been prescribed. The expected clinical environment for the RTC 24-V MDI Adapter is Critical Care and/or long term or short term ventilation.

The RTC 24-V MDI Adapter is intended for single patient reuse.

This device is intended for sale by or on the order of a physician.

Prescription Use √ And/Or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K091111

Indications for Use

510(k) Number (if known):

K091111

Device Name:

RTC 24-V Metered Dose Inhaler Adapter Kit
(To be sold as model number RTC 24-V KIT)

Statement of Indications for Use:

The Instrumentation Industries, Inc. RTC 24-V KIT includes the RTC 24-V MDI Adapter actuator for intermittent delivery of prescribed aerosol medication dispensed in cylindrical-style metered dose inhalers. The RTC 24-V KIT is intended for use only when connected to ventilator tubing or tracheal tubes.

The RTC 24-V KIT is intended to be prescribed for any patient who is ventilator-dependent and to whom a metered dose inhaler has been prescribed. The expected clinical environment for the RTC 24-V KIT is Critical Care and/or long term or short term ventilation.

The components of the RTC 24-V KIT consist of one RTC 24-V MDI Adapter, one four inch length of 22 mm inner-diameter tubing, and one 15 mm inner-diameter/22 mm outer-diameter adapter.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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