K101857

Instrumentation Industries, Inc.
We make Respiratory Care Work!

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JUL 22 2010

Date Prepared: June 30, 2010
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

SPECIAL 510(k) SUMMARY
for
RTC 24-VP Metered Dose Inhaler Adapter

Trade Name	RTC 24-VP Metered Dose Inhaler Adapter
Common Name	Actuator
Classification Name	Nebulizer
Regulation	21 CFR 868.5630
Predicate Device	Instrumentation Industries, Inc. RTC 24-V (K091111)
Device Description	The Instrumentation Industries, Inc. RTC 24-VP metered dose inhaler adapter is an actuator for intermittent delivery of prescribed aerosol medication dispensed in metered dose inhalers.
Intended Use of the Device RTC 24-VP Metered Dose Inhaler Adapter	The Instrumentation Industries, Inc. RTC 24-VP MDI Adapter is an actuator for intermittent delivery of prescribed aerosol medication dispensed in cylindrical-style metered dose inhalers. The RTC 24-VP MDI Adapter is intended for use only when connected to ventilator tubing or tracheal tubes. The RTC 24-VP 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-VP MDI Adapter is Critical Care and/or long term or short term ventilation. The RTC 24-VP MDI Adapter 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 and the materials of both the RTC 24-V predicate device and the RTC 24-VP are the same. Both the RTC 24-V and the RTC 24-VP will accept

	plastic or metal tipped, cylindrically-shaped MDI canisters. All materials are latex-free. Materials – Body – Polystyrene Butadiene Cap – Thermoplastic Rubber Functional Dimensions - Outlet – 15mm I.D. / 22 mm O.D. Markings – Both the RTC 24-V and the RTC 24-VP are marked with a molded-in arrow defining direction of flow. **Differences:** The RTC 24-VP has a decreased inlet port size of 15 mm OD. The RTC 24-V has an inlet port of 22 mm ID.
Performance	When a range of flow rates is used to ventilate air through both the new RTC 24-VP MDI adapter and the original RTC 24-V MDI adapter, very little difference is seen in peak circuit back pressure. The decreased inlet port size on the RTC 24-VP has no significant impact on the rate of flow through the device or on the circuit back pressure.
Conclusion:	In laboratory testing the RTC 24-VP MDI adapter is substantially equivalent to the RTC 24-V MDI adapter 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

JUL 22 2010

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

Re: K101857
Trade/Device Name: RTC 24-VP Metered Dose Inhaler Adapter
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 30, 2010
Received: July 2, 2010

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. 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

Indications for Use

510(k) Number (if known):

Device Name:

RTC 24-VP Metered Dose Inhaler Adapter

Statement of Indications for Use:

RTC 24-VP Metered Dose Inhaler Adapter

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

The RTC 24-VP 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-VP MDI Adapter is Critical Care and/or long term or short term ventilation.

The RTC 24-VP 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)

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

510(k) Number: K101857

Concurrence of CDRH, Office of Device Evaluation (ODE)