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

February 28, 2017

Instrumentation Industries, Inc.
% Doris Walter
Regulatory Affairs/Quality Assurance Manager
2990 Industrial Blvd.
Bethel Park, Pennsylvania 15102

Re: K162753
Trade/Device Name: RTC 26-C Inline Aerosol Adapter
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: January 17, 2017
Received: January 19, 2017

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162753

Device Name
RTC 26-C Inline Aerosol Adapter

Indications for Use *(Describe)*

Indications for Use:

The RTC 26-C Inline Aerosol Adapter is designed to assist in the delivery of Combivent® (ipratropium bromide and albuterol) medication from a Respimat® inhaler as prescribed to an adult, mechanically-ventilated patient. The RTC 26-C Inline Aerosol Adapter is intended for use only when connected to ventilator tubing.

The RTC 26-C Inline Aerosol Adapter is intended for single patient reuse.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 2/28/2017
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

510(k) SUMMARY
of the
RTC 26-C Inline Aerosol Adapter

Trade Name	RTC 26-C Inline Aerosol Adapter
Common Name	Adapter
Classification Name	Accessory to a Nebulizer
Regulation	21 CFR 868.5630
Predicate Device	Instrumentation Industries, Inc. RTC 22-D (K991355) Metered Dose Inhaler Adapter
Device Description	The Instrumentation Industries, Inc. RTC 26-C Inline Aerosol Adapter is a single-patient reuse device intended to provide an access port in a ventilator circuit to facilitate the administration of Combivent® (ipratropium bromide and albuterol) Respimat® medication to mechanically ventilated patients.
Indications for Use	The RTC 26-C Inline Aerosol Adapter is designed to assist in the delivery of Combivent® (ipratropium bromide and albuterol) medication from a Respimat® inhaler as prescribed to an adult, mechanically-ventilated patient. The RTC 26-C Inline Aerosol Adapter is intended for use only when connected to ventilator tubing. The RTC 26-C Inline Aerosol Adapter is intended for single patient reuse. This device is intended for sale by or on the order of a physician.
Intended Use of the Device	The RTC 26-C Inline Aerosol Adapter is intended to be prescribed for any adult patient who is ventilator-dependent and for whom a Combivent® (ipratropium bromide and albuterol) Respimat® has been prescribed. The expected clinical environment for the RTC 26-C Inline Aerosol Adapter is Critical Care and/or long term or short term ventilation. The RTC 26-C Inline Aerosol Adapter is intended for single patient reuse. “Single patient reuse” means that this adapter can be used to deliver Combivent® (ipratropium bromide and albuterol) Respimat® medication multiple times to a single patient while installed in a breathing circuit, for a period of time not to exceed 14 days. This device is intended for sale by or on the order of a physician.

<table>
<tr><td>Discussion of Similarities of Intended Use of the RTC 26-C and the Predicate Device</td><td>1. Both devices are intended for use in a ventilator circuit when ordered by a physician.
2. Both devices remain in the circuit once installed, and are discarded with the circuit upon circuit change.
3. Both devices are intended for a single patient. Neither device is intended to be reprocessed after use.
4. Both devices allow certain medications from a metered dose inhaler, specifically albuterol sulfate and ipratropium bromide, to be delivered to a ventilated patient after a medical professional determines the need for them.
5. Both devices must be capped after the MDI device is removed.</td></tr>
<tr><td>Technological Characteristics</td><td>Similarities between the RTC 26-C and the Predicate Device:
1. The inlet and outlet end dimensions for both the RTC 26-C and RTC 22-D adapters accommodate 22mm breathing circuit connections.
2. Both devices are marked with a molded arrow to indicate direction of flow.
3. Both devices include a molded body and a molded cap. Each of the bodies, and each of the caps, are molded of the same respective materials.
4. None of the materials making up these devices are manufactured with natural rubber latex.
5. Both devices are sold as ‘Not Sterile’.

Differences between the RTC 26-C and the Predicate Device:
1. The RTC 22-D serves as an actuator for a metered dose inhaler. The RTC 26-C is not an actuator: Its function is to allow access to a breathing circuit for the purpose of the introduction of the prescribed medication.
2. The RTC 22-D can be used with MDI medication canisters which have standard cylindrical stem outlets. The RTC 26-C is intended to be used only with Combivent® (ipratropium bromide and albuterol) bronchodilator medication dispensed from a Respimat® inhaler which has an elliptical mouthpiece outlet.</td></tr>
<tr><td>Performance Testing</td><td>Specific tests performed upon the RTC 26-C, and their outcomes, include the following:

<table>
<tr><td>Placement and Usage Trials within Two Typical Types of Ventilator Circuits</td><td>The set-up and usage of the RTC 26-C was no more difficult than that of the predicate in its typical circuit set-up. The Respimat inhaler was able to be easily and securely placed into the medication port to deliver a properly dispersed dose of medication.</td></tr>
<tr><td>Ventilator Cycling Test</td><td>RTC 26-C Adapters and the predicate device were put through 18 days of high pressure ventilator cycling with circuit conditions changes that included heat, cold, low and high humidification, and an HME set-up. Each adapter tested remained secure within the test-set;

No caps became dislodged. Every medication dose dispersed properly.</td></tr>
<tr><td>Adapter Resistance Test</td><td>The RTC 26-C Adapter had less resistance than that of the predicate device for every trial run at both 60 and 80 lpm peak flow settings.</td></tr>
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Cap Pressure/Leak Test	Simulated testing with ventilator cycling at high peak pressures, under both dry and wet circuit conditions, prove that the cap of the RTC 26-C adapter fits more securely, and leaks less than the cap of the predicate device
Temperature Extremes Functionality Test	Both new and predicate adapters cycled through extreme low and high temperatures performed equally well.
Shipping Trials	Test results indicate that the RTC 26-C withstands the rigors of shipping and handling, will continue to fit 22mm mating components as part of a ventilator circuit and is substantially equivalent to the predicate device.
Adapter Cap Tether Strength Trials	No negative consequences were seen after stretching tethers to twice their normal length.
PEEP Loss Test	This test determined PEEP loss between breaths using a non-leak-compensated ventilator, compared to that of a ventilator in leak-compensating mode, to prove that any potential PEEP loss (in the event of a cap not being replaced) is small enough to be entirely prevented by the ventilator.
Drop Test	The materials and design of the RTC 26-C are durable and raise no new safety and effectiveness issues.
Respimat® Inhaler Attachment Trials	After 500 attachment cycles, there was no damage to the medication inlet port of any of the 10 samples tested. Medication dosage dispersion testing was also successful for every trial.
Port Connection Trials	This test of the 22mm OD ports on RTC 26-C samples proved that the adapters retained their secure fit to mating connectors after 25 cycles, fitting as snugly as they did after the first one.

Performance Testing, continued

Adult Aerosol Performance Comparison Testing of the RTC 26-C and RTC 22-D Predicate Device

	Albuterol		Ipratropium	
	RTC 26-C	RTC 22-D	RTC 26-C	RTC 22-D
Total Delivered Dose from RTC 26-C Adapter (µg)	58.1 - 67.2	50.9 - 62.3	11.4 - 13.9	10.4 - 11.9
% Reduction in Total Delivered Dose compared to respective SMI/MDI alone	27.8%	45.5%	34.0%	40.4%
Respirable Particle Mass from RTC 26-C (µg, 0.5-5µm)	24.7 - 28.5	16.6 - 20.9	5.0 - 5.9	1.6 - 3.1
Respirable Fraction (0.5-5µm)	42.4%	33.0%	43.7%	21.4%
% Reduction in Respirable Dose compared to respective SMI/MDI alone	47.5%	55.7%	50.4%	68.8%
Coarse Particle Dose (µg, >4.7µm)	22.3 - 28.8	31.8 - 41.4	4.0 - 6.3	7.1 - 8.3
Particle Fraction > 4.7µm	40.8%	64.7%	40.5%	68.8%
Fine Particle Dose (µg, <4.7µm)	35.1 - 39.1	17.7 - 22.3	6.8 - 8.1	2.7 - 4.2
Particle Fraction < 4.7µm	59.2%	35.3%	59.5%	30.4%
Extra-Fine Particle Dose (µg, <1.0µm)	17.7 - 20.6	2.1 - 19.5	3.5 - 4.2	1.5 - 2.1
Particle Fraction <1.0µm	30.5%	19.1%	30.2%	16.1%
Mass-Median Aerosol Diameter (MMAD) (µm)	1.4 - 1.7	1.8 - 2.1	1.4 - 1.7	0.9 - 1.4
Geometric Standard Deviation (GSD)	3.8 - 4.6	2.4 - 3.1	3.9 - 4.6	3.6 - 5.0

95% confidence intervals. Cascade impactor testing conducted at 28.3 lpm.

RTC 26-C: Testing done with one Combivent Respimat SMI, three samples of RTC 26-C, three tests per sample, for a total of nine measurements per medication and output variable.

RTC 22D: Testing done with two drugs (one canister each of Ventolin HFA and Atrovent), three samples of RTC 22-D, with three tests per device sample, for a total of nine measurements per medication and output variable.

Bio-compatibility Information

Materials used in the manufacture of the RTC 26-C Inline Aerosol Adapter, thermoplastic elastomer and polystyrene butadiene, have previously been used in the manufacture of medical devices, specifically the predicate device (K991355).

Category: External Communicating Device
Contact: Tissue/Bone/Dentin
Contact Duration: Prolonged (>24 hours to 30 days)

The RTC 26-C is intended to be installed and remain in the breathing circuit until the breathing circuit is replaced in accordance with facility guidelines, for a period of time not to exceed 14 days.

Conclusion:

In both laboratory and simulated usage testing, the RTC 26-C has been compared against a currently marketed device for the determination of substantial equivalency. This testing has not raised different issues of safety and effectiveness and the RTC 26-C has been found to be substantially equivalent to the RTC 22-D.