



June 4, 2024

Medline Industries, LP
Phyllis Kondor
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K234032

Trade/Device Name: Hudson RCI Dri-Tech Breathing Circuits; HUD99035/Dri-Tech Adult Circuit; HUD99035KIT/Dri-Tech Adult Circuit Kit; HUD99098KIT/Single Limb Adult Dri-Tech Kit; HUD99098KITF/Single Limb Adult Dri-Tech Filter Kit; HUD900/Dri-Tech Ventilator Accessory; HUD901/Dri-Tech Ventilator Accessory Extension Line

Regulation Number: 21 CFR 868.5270

Regulation Name: Breathing System Heater

Regulatory Class: Class II

Product Code: BZE

Dated: December 20, 2023

Received: December 20, 2023

Dear Phyllis Kondor:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.

Assistant Director

DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K234032

Device Name

Hudson RCI Dri-Tech Breathing Circuits:

HUD99035/Dri-Tech Adult Circuit

HUD99035KIT/Dri-Tech Adult Circuit Kit

HUD99098KIT/Single Limb Adult Dri-Tech Kit

HUD99098KITF/Single Limb Adult Dri-Tech Filter Kit

HUD900/Dri-Tech Ventilator Accessory

HUD901/Dri-Tech Ventilator Accessory Extension Line

Indications for Use (Describe)

The Hudson RCI Dri-Tech Breathing Circuits are intended for pediatric and adult patients in professional healthcare environments as a conduit of breathing gas between a patient and a ventilator and to maintain the temperature of humidified inspired gas.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

Section 17

510(k) Summary

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Submission Correspondent

Phyllis Kondor
Regulatory Affairs Specialist
pkondor@medline.com
1-800-633-5463

Summary Preparation Date

May 8, 2024

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Hudson RCI® Dri-Tech™ Breathing Circuits

Model Numbers:

- HUD99035 / Dri-Tech Adult Circuit
- HUD99035KIT / Dri-Tech Adult Circuit Kit
- HUD99098KIT / Single Limb Adult Dri-Tech Kit
- HUD99098KITF / Single Limb Adult Dri-Tech Filter Kit
- HUD900 / Dri-Tech Ventilator Accessory
- HUD901 / Dri-Tech Ventilator Accessory Extension Line

Classification Name: Breathing system heater

Product Code: BZE

Classification Panel: Anesthesiology (Respiratory)

Regulatory Class: Class II

Regulation Number: 21 CFR 868.5270

Predicate Device

Hybernite RT Single Limb and Dual Heated Breathing Circuits (K151461)

Device Description

The Hudson RCI® Dri-Tech Breathing Circuits are intended for pediatric and adult patients in professional healthcare



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

environments as a conduit for respiratory gas between a patient and a ventilator and includes heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier (K131912). The heated wires are intended to aid in maintaining the set patient temperature and minimize condensation in the ventilator tubing.

The Dri-Tech Breathing Circuits are designed to be used with various patient interfaces such as oral tracheal tubes, nasal tracheal tubes, endo-bronchial tubes, and masks (for noninvasive ventilation therapies such as CPAP, BiPAP, and Mask usage). As such, Dri-Tech Breathing Circuits are designed and will be manufactured to conform to the test requirements of ISO 5367:2014 “Anaesthetic and respiratory equipment -- Breathing sets and connectors”.

The adult dual limb configuration consists of 19mm ID inspiratory and expiratory limbs with 22mm connectors that are compliant to ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets. The adult circuits have a length of 1.7m on the inspiratory limb and 2.0m on the expiratory limb, and are kitted with the accessories described below:

- Tubing Adaptor: 22mm male to male adaptor for various connections as required.
- Elbow Adaptor: Adaptor for connecting to the circuit wye to the patient interface to allow the circuit to exit the patient perpendicularly for optimal placement.
- Tubing Hanger: Optional accessory for hanging the circuit to reduce pull on the patient interfaces and ventilator/humidifier connections.
- Humidifier Limb: Required tubing and adaptors for connecting the ventilator inhalation port to the heated humidifier.

Optional Ventilator Accessory available for the Dri-Tech Dual Limb Breathing Circuit:

- Dri-Tech Ventilator Accessory: Optional tee accessory capable of providing the 10 LPM flow required for the expiratory star lumen tubing. This ventilator accessory is comprised of male and female medical grade air DISS connectors to connect between the air hose and ventilator, a standard Christmas tree adaptor for connecting the tubing to, and an on/off valve to start and stop the flow.

The adult single limb configuration is identical to the inspiratory limb of the dual limb configuration, however, is packaged with a different set of adaptors to facilitate connections and use with non-invasive therapies as described below:

- Humidifier Line: Optional tubing and adaptors for connecting the ventilator inhalation port to the heated humidifier.
- Exhalation Port Adaptor: Optional adaptor including an exhalation port and connector for the pressure monitoring line.
- Pressure Monitoring Line: Optional accessory tubing for use with units without an Airway Pressure Monitor.
- Pressure Monitoring Assembly: Optional accessory containing a tee and tubing for pressure monitoring on units with an Airway Pressure Monitor.
- 15mm Adaptor: Optional accessory required for connecting to certain patient interfaces.
- Male Luer: Optional accessory for required for certain setups to connect the pressure monitoring line.
- Tubing Hanger: Tubing hanger designed for single limb tubes and pressure monitoring lines to reduce pull on the patient interfaces and ventilator/humidifier connections.



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

- Bacterial/Viral Electrostatic Filter: Optional accessory in specific kit codes for user convenience.

The Hudson RCI® Dri-Tech Breathing Circuits are sold non-sterile.

Indications for Use

The Hudson RCI® Dri-Tech Breathing Circuits are intended for pediatric and adult patients in professional healthcare environments as a conduit of breathing gas between a patient and a ventilator, and to maintain the temperature of humidified inspired gas.

Principle of Operation

The basic principle of operation of the Hudson RCI Dri-Tech Breathing circuit is the inspiratory limb attaches to the Hudson RCI Neptune Heated Humidifier (which is attached to the ventilator inhalation port) and the expiratory limb attaches to the ventilator. The circuit acts as a conduit to ventilate the patient, and maintains the heat and humidity through the use of heated wire within the circuit.

Summary of Technological Characteristics

TABLE 17-1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Subject Device Hudson RCI® Dri-Tech™ Breathing Circuits (Adult)	Predicate Device Hybernite RT Single Limb and Dual Heated Breathing Circuits (K151461)	Comparison Analysis
Manufacturer	Medline Industries, LP	Plastiflex Healthcare	
Product Code	BZE	BZE	Identical.
Classification	Class II	Class II	Identical.
Indications for Use	The Hudson RCI Dri-Tech Breathing Circuit is intended for pediatric to adult patients in a professional healthcare environment as a conduit for warmed and humidified respiratory gases between a patient and a ventilator and includes heated wires for use with the Hudson RCI Neptune Heated Humidifier. These devices are indicated for single patient use only.	The Hybernite RT heated breathing circuits are intended to carry warmed / moistened gas from the humidifier to the patient's airways. The Hybernite RT breathing tubes are indicated for patient populations from neonates to adults. They may be used in the home or hospital environments. They are for single patient use only.	Similar. Both the subject device and the predicate device are intended to serve as a conduit for warm, humidified respiratory gas from a ventilator to the patient's airways. The predicate device (K151461) is cleared for use in both home and professional healthcare environments while the subject device is seeking clearance for use in professional healthcare environments only. The predicate device is



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

			cleared for use in neonates to adults while the subject device is seeking clearance for use in pediatric through adult patients. The subject device does not include neonates or infants in its indications for use. Both the subject and predicate device are indicated for single patient use. Our device is not adding additional patient populations or environments of use versus the device cleared in K151461, as the predicate device is cleared for broader patient populations and environments of use. The differences in the indications for use for the subject device and predicate device are solely the expanded environment of use and patient population cleared under K151461. The exclusion of the home environment and the neonate and infant population from the subject device does not raise any additional questions of safety and effectiveness in the subject device as these are characteristics cleared in K151461,
--	--	--	--



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

			therefore the indications for use are substantially equivalent.
Reusability	Single patient use, disposable	Single patient use, disposable	Identical.
Regulation Number	868.5270	868.5270	Identical.
Prescription vs. OTC	Prescription	Prescription	Identical.
Contraindications	No known contraindications	No known contraindications	Identical.
Sterile vs. Non-Sterile	Not sterile	Not sterile	Identical.
Patient Population	Pediatric and adults	Neonates to adults	Similar. The subject device is not intended for neonates and infants. The exclusion of the neonate and infant patient population from the subject device does not raise any additional questions of safety and effectiveness
Environment of Use	Professional healthcare environment	Home and Healthcare Environment	Similar. The Hudson RCI Dri-Tech Breathing Circuit is not being used in the home environment, while the predicate device includes the home as an environment of use. The Professional Healthcare environment remains unchanged for the proposed device. The exclusion of the home environment from the subject device does not raise any additional questions of safety and effectiveness.



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

Useful Life			Similar. While the predicate device is cleared for a longer useful life (30 days) than the proposed device, the Dri-Tech breathing circuits have met all applicable useful life and biocompatibility requirements for the intended 12-day useful life and will be labeled as intended. A longer useful life is more challenging to meet as longer use leads to more opportunities for an issue to arise. Therefore, a shorter useful claim does not raise any additional questions of safety and effectiveness.
	Dispose of the product once patient therapy has been completed or after a maximum of 12 days	Dispose of the product once patient therapy has been completed or after a maximum of 30 days	
Compatible Connectors	Standard connector (22mm)	Standard Connector (22mm)	Identical.
Compatible Accessories	• Tubing adaptors • Humidifier limb • Tubing hanger • Accessory tee(s) • Ventilator accessory and extension line • Pressure monitoring line(s) and adaptors	• Tubing adaptors • Humidifier limb	Similar. The proposed Dri-Tech breathing circuits may be packaged or assembled with additional Class I devices as compared to the predicate. As additional accessories can potentially affect safety and effectiveness, testing was completed using all accessories to ensure their use did not introduce any new risks or negatively



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

			affect performance. Verification testing was completed specific to usage of the ventilator accessory, and useful life testing was completed with the ventilator accessories, all adaptors, tubing hangers, and pressure monitoring accessories to ensure safety and efficacy.
Circuit Configurations	Single Limb and Dual Limb Heated Wire Circuit	Single Limb and Dual Lime Heated Wire Circuit	Identical.
Power Source	Humidifier controlled	Humidifier controlled	Identical.
Mode of Action	When a voltage is applied, a current flows through the heating wires. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed and humidified reducing or eliminating water condensation and/or pooling of water in the breathing circuit.	When a voltage is applied, a current flows through the heating wires. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed reducing or eliminating water condensation and/or pooling of water in the breathing circuit.	Identical.
Energy Used/Delivered	Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. The raising of the gas temperature does not	Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. The raising of the gas temperature does not	Similar. The proposed device is tested to the most current revision (ISO 80601-2-74:2017) of the applicable standard that the predicate was originally tested to. By meeting



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

	exceed a specific enthalpy of 197 kJ/m ³ (equivalent to 43°C at 100% relative humidity)	exceed 40°C.	the requirement of the latest standard revision, the circuit is shown to be safe and effective without raising any additional questions of safety and effectiveness.
Length and Diameter	Length: Inspiratory: 1.7m Expiratory: 2.0m Circuit Inner Diameter: 19 mm Ø	The Hybernite RT tubing has a range of tubing dimensions, depending on the clinical application connected to the humidifier: - Internal diameter from 10 mm to 22 mm - Length from 0.3 meters to 2.4 meters	Similar. The proposed device ID varies slightly from the predicate device but is within the range that our predicate device claims and has testing to support. The length and diameter of the circuit can potentially affect compressible gas volume within the circuit and resistance to flow; however, the proposed device was tested for compliance and resistance to flow to ISO 5367:2014 and met the requirements of the standard for breathing circuits. As the length and diameters are within the predicate range and tested to the latest standards, no additional questions of safety and



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

			effectiveness are raised by the differences.
Heating Wire	Encased	Encased	Identical.
Resistance to Flow (Inspiratory Limb)	Dri-Tech Adult: Less than 1.8 cmH ₂ O @ 30 LPM (per ISO 5367:2014)	Hybernite Adult: Less than .06 hPa/LPM @ 30 LPM (per ISO 5367:2014)	Identical. Following ISO 5367:2014, the proposed breathing circuit is tested at 15LPM and 30 LPM. At each flow rate the resistance to flow is below 1.8 cmH ₂ O (1.8 hPa) as required by the standard
Compliance	Dri-Tech Adult: Less than 5 mL/cmH ₂ O @ 60 cmH ₂ O (per ISO 5367:2014)	Hybernite Adult: Less than 5 mL/hPa @ 60 hPa (per ISO 5367:2014)	Identical. Following ISO 5367:2014, the proposed breathing circuits were tested at 60 cmH ₂ O. At 60 cmH ₂ O the compliance is below 1.5 mL/cmH ₂ O (infant) and 5 mL/cmH ₂ O (adult) as required by the standard
Leakage	Less than 30 ml/min @ 60 cmH ₂ O (per ISO 5367:2014)	Unknown	Following ISO 5367:2014, the proposed breathing circuits was tested at 60 cmH ₂ O. At 60 cmH ₂ O the leakage is 40 ml/min or less as required by the standard
Standards	BS EN ISO 5367:2014 BS EN ISO 5356-1:2015	ISO 5367 ISO 5356	Identical. Latest revisions are used for



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

	BS EN ISO 80601-2-74:2017 BS EN ISO 10993-1:2018 BS EN ISO 18562-1:2017 BS EN 60601-1:2006 BS EN 60601-1-2:2015 BS EN 62366-1:2015 IEC 60601-4-2:2016	ISO 8185 ISO 10993 IEC 60601-1 IEC 60601-1-2 IEC 62366	all applicable standards, and superseded standards have been replaced (ISO 80601 replacing ISO 8185)
--	---	--	---

As evidenced by the predicate device comparison table above, the Hudson RCI® Dri-Tech™ Breathing Circuits have the same characteristics as the predicate device, including intended use, operating principles, and fundamental scientific technology. The Hudson RCI® Dri-Tech™ Breathing Circuits have undergone non-clinical testing that covers electrical and thermal safety, environmental conditions, functional verification, and performance testing.

The Hudson RCI® Dri-Tech™ Breathing Circuits are identical to the predicate device in the following characteristics:

- Intended use for carrying heated gas between a patient and a ventilator
- Mode of Action
- Circuit Configurations
- Power source
- Heating Wire
- Standards
- Compliance
- Resistance to Flow

The differences between the Dri-Tech™ Breathing Circuits and the predicate device are:

- Patient population – the predicate device is cleared for use in neonates to adult patients while the subject device is not intended for neonates and infants. The exclusion of the neonate and infant patient population from the subject device does not raise any additional questions of safety and effectiveness. The subject device and predicate are substantially equivalent as both are intended for use in children, adolescents, and adults.
- Environment of use – the predicate device is cleared for home use and use in professional healthcare environments while the subject device is only intended for use in professional healthcare environments. The exclusion of the home environment for the subject device does not raise any additional questions of safety and effectiveness as the subject and predicate are substantially equivalent as it relates to use in professional healthcare environments.
- Useful life – while the predicate device is cleared for a longer useful life (30 days) than the proposed device, the Dri-Tech breathing circuits have met all applicable useful life and biocompatibility requirements for the intended 12 day useful life and will be labeled as intended. The proposed useful life for Dri-Tech does not exceed the cleared useful life for the predicate device and therefore does not raise any additional questions of safety and effectiveness.

These differences do not raise different risks or concerns of safety and effectiveness compared to the predicate. Based on the information provided, the Dri-Tech Breathing Circuits are substantially equivalent to the Hybernite Single Limb and Dual Heated Breathing Circuits.



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

Summary of Non-Clinical Testing

Biocompatibility Testing

Cytotoxicity
Irritation or Intracutaneous Reactivity
Sensitization
Genotoxicity
Implantation *
Material Mediated Pyrogenicity
Extractables/Leachables
Acute Systemic Toxicity *
Subacute Toxicity*
Subchronic Toxicity*
Chronic Toxicity*
Carcinogenicity*

* Per ISO 10993-1:2018, these tests were evaluated

Additionally, due to the nature of contact, the Dri-Tech breathing circuits were also evaluated per Gas Pathway Evaluation per ISO 18562-1:2017 *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*.

The following gas pathway endpoints were tested or evaluated(*) based on the device categorization and intended use:

- Particulate matter
- VOCs
- Leachables in Condensate*

The exterior circuit components are classified as intact skin contact with a Permanent contact duration (>30 days).

The following biological endpoints were evaluated based on the device categorization and intended use:

- Cytotoxicity
- Irritation or Intracutaneous Reactivity
- Sensitization

Performance Testing (Bench)

Distribution Simulation Testing – Shipping and Packaging Integrity
Time 0 Useful Life Validation Testing
1 Year Accelerated Aged Useful Life Validation Testing
ISO 5356-1:2015 Gauge Testing



Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Traditional 510(k) Premarket Notification
Hudson RCI® Dri-Tech™ Breathing Circuits
All information on this page is
confidential.

ISO 5367:2014 Testing
- Length
- Leakage Rate
- Compliance
- Resistance to Flow
- Resistance to Flow with a Bend
- Adaptor Retention
Circuit Weight Testing
Dri-Tech Ventilator Accessory Flow Rate Testing
Expiratory Star Lumen Tubing Kink and Crush Resistance
Moisture Removal Performance Testing
Dri-Tech Ventilator Accessory and Circuit Related Pressures Testing
Expiratory Star Lumen Tubing Flow Rate (Information Only)
ISO 80601-2-74:2017 Safety Testing
IEC 60601-1:2005 Electrical Safety Testing
IEC 60601-1-2:2014 Electromagnetic Compatibility and Immunity Testing
Summative Human Factors and Usability Testing

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Summary of Clinical Testing

Not applicable.

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Hudson RCI® Dri-Tech™ Breathing Circuits are substantially equivalent to the Hybernite RT Single Limb and Dual Heated Breathing Circuits (K151461) with respect to the indications for use, patient population, environment of use, circuit configurations and technological characteristics.