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

Re: K253322
Trade/Device Name: Hudson RCI® Infant Dri-Tech™ Breathing Circuits (HUD99060 / Dri-Tech with 78" Infant Circuit, HUD99060KIT / Dri-Tech with 78" Infant Circuit Kit, HUD99001KIT / Single Limb Infant Circuit Dri-Tech Kit, HUD99009KIT / Dri-Tech with 60" Infant Circuit Kit, HUD99018KIT / Dri-Tech with 44" Infant Circuit Kit, HUD870NKIT / Dri-Tech Infant Accessory Bag, HUD1631 / Infant Wye Connector with Swivel)

Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: February 25, 2026
Received: February 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

John S. Bender -S

*for* Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K253322 |

Please provide the device trade name(s).

Hudson RCI® Infant Dri-Tech™ Breathing Circuits

HUD99060 / Dri-Tech with 78” Infant Circuit
HUD99060KIT / Dri-Tech with 78” Infant Circuit Kit
HUD99001KIT / Single Limb Infant Circuit Dri-Tech Kit
HUD99009KIT / Dri-Tech with 60” Infant Circuit Kit
HUD99018KIT / Dri-Tech with 44” Infant Circuit Kit
HUD870NKIT / Dri-Tech Infant Accessory Bag
HUD1631 / Infant Wye Connector with Swivel

Please provide your Indications for Use below.

The Hudson RCI® Infant Dri-Tech™ Breathing Circuits are intended for neonatal, infant, and pediatric patients weighing 32kg or less 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

# 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**
September 30, 2025

**Type of 510(k) Submission**
Traditional

**Device Name / Classification**
Trade Name: Hudson RCI® Infant Dri-Tech™ Breathing Circuits
Model Numbers:

- HUD99060 / Dri-Tech with 78” Infant Circuit
- HUD99060KIT / Dri-Tech with 78” Infant Circuit Kit
- HUD99001KIT / Single Limb Infant Circuit Dri-Tech Kit
- HUD99009KIT / Dri-Tech with 60” Infant Circuit Kit
- HUD99018KIT / Dri-Tech with 44” Infant Circuit Kit
- HUD870NKIT / Dri-Tech Infant Accessory Bag
- HUD1631 / Infant Wye Connector with Swivel

Classification Name: Breathing system heater
Product Code: BZE
Classification Panel: Anesthesiology
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® Infant Dri-Tech Breathing Circuits are intended for neonatal, infant, and pediatric patients weighing 32kg or less in professional healthcare 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 Infant 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, Cannula 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 dual limb configuration consists of 12mm ID inspiratory and expiratory limbs with 22mm machine side connectors that are compliant to ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets, and 12mm patient side connectors that utilize the same taper and engagement length as ISO 5356-1:2015 connectors. The infant circuits have two length configurations, a short inspiratory that is 1.12m or a long inspiratory that is 1.6m, either of which can be used with an expiratory limb that is 1.7m, and may be kitted with the accessories described below:

- **Accessory Tee with Closure Cap**: Optional tubing adaptor for various connections as required.
- **Remote Port Tubing, 6” and 12”**: Unheated sections of tubing for use with incubators, isolettes, or other ambient heating to ensure the temperature probe is not heated by the environment.
- **Unheated Ventilator Tubing**: Required tubing and adaptors for connecting the ventilator inhalation port to the heated humidifier.

The single limb configuration is identical to the long version of 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:

- **Unheated Ventilator Tubing**: Optional tubing and adaptors for connecting the ventilator inhalation port to the heated humidifier.
- **Pressure Monitoring Line**: Optional accessory tubing for use with units without an Airway Pressure Monitor.

All Hudson RCI Dri-Tech breathing circuit configurations are packaged in polyethylene (PE) bags to protect the devices from environmental influences like dust and moisture. Included in the PE bags are additional PE bags containing ConchaSmart columns (-KIT configurations only) and included accessories. The breathing circuit PE bags are packaged ten (10) to a cardboard carton for all configurations. They are sold non-sterile.

## Indications for Use

The Hudson RCI® Infant Dri-Tech™ Breathing Circuits are intended for neonatal, infant, and pediatric patients weighing 32kg or less 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.

**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 | Proposed Device Hudson RCI® Dri-Tech™ Breathing Circuits | 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 Infant Dri-Tech Breathing Circuits are intended for neonatal, infant, and pediatric patients weighing 32kg or less 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. | 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.<br><br>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 cleared for use in neonates to adults while the subject device is seeking clearance for use in neonatal, infant, and pediatric patients (32 kg or less). The subject device does not include adults or patients weighing more than 32kg in its indications for use. Both the subject and predicate device are indicated for single patient use.<br>Our device is not adding additional patient populations or environments |

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| | | | 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 patients weighing more than 32kg 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, therefore the indications for use are substantially equivalent. |
| **Reusability** | Single patient use, disposable | Single patient use, disposable | Identical. |
| **Patient Population** | Neonatal, Infant, and Pediatric Patients | Neonates to adults | Similar. The subject device is not intended for adults or pediatric patients weighing more than 32kg. The exclusion of the adult 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.<br>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 |

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| | | | exclusion of the home environment from the subject device does not raise any additional questions of safety and effectiveness. |
| **Useful Life** | Dispose of the product once patient therapy has been completed or after a maximum of 14 days | Dispose of the product once patient therapy has been completed or after a maximum of 30 days | 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 14-day useful life and will be labeled as intended. A longer useful life is a 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. |
| **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. |
| **Compatible Connectors** | Standard connector (22mm) | Standard Connector (22mm) | Identical. |
| **Compatible Accessories** | • Tubing adaptors<br>• Unheated Ventilator Tubing<br>• Accessory tee(s)<br>• Ventilator accessory and extension line<br>• Pressure monitoring line(s) and adaptors | • Tubing adaptors<br>• Humidifier limb | Similar.<br>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 affect performance. Verification |

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| | | | 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 Limb 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 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.<br>The raising of the gas temperature does not exceed a specific enthalpy of 197 $kJ/m^3$ (equivalent to 43ºC at 100% relative humidity) | 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.<br>The raising of the gas temperature does not exceed 40ºC. | 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 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:<br>Inspiratory: 1.6m or 1.12m<br>Expiratory: 1.6m<br>Circuit Inner Diameter: 12 mm Ø | The Hybernite RT tubing has a range of tubing dimensions, depending on the clinical application connected to the humidifier: | Similar. The proposed device ID varies slightly from the predicate device but is within the range that our predicate device claims and has testing |

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| | | • Internal diameter from 10 mm to 22 mm<br>• Length from 0.3 meters to 2.4 meters | 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 effectiveness are raised by the differences. |
| **Heating Wire** | Encased | Encased | Identical. |
| **Resistance to Flow (Inspiratory Limb)** | Dri-Tech Infant:<br>Less than 1.8 $cmH_2O$ @ 2.5 LPM and 15LPM (per ISO 5367:2014) | Hybernite Infant:<br>ISO 5367 Compliant | Identical. Following ISO 5367:2014, the proposed breathing circuits were tested at 2.5 LPM and 15 LPM. At each flow rate the resistance to flow is below 1.8 $cmH_2O$ (1.8 hPa) as required by the standard |
| **Compliance** | Dri-Tech Infant:<br>Less than 1.5 $mL/cmH_2O$ @ 60 $cmH_2O$ (per ISO 5367:2014) | Hybernite Infant:<br>ISO 5367 Compliant | Identical. Following ISO 5367:2014, the proposed breathing circuits were tested at 60 $cmH_2O$. At 60 $cmH_2O$ the compliance is below 1.5 $mL/cmH_2O$ as required by the standard |
| **Leakage** | Less than 30 ml/min @ 60 $cmH_2O$ (per ISO 5367:2014) | Unknown | Following ISO 5367:2014, the proposed breathing circuits were tested at 60 $cmH_2O$. At 60 $cmH_2O$ the leakage shall be 30 ml/min or less as required by the standard |
| **Standards** | BS EN ISO 5367:2014<br>BS EN ISO 5356-1:2015<br>BS EN ISO 80601-2-74:2017<br>BS EN ISO 10993-1:2018 | ISO 5367<br>ISO 5356<br>ISO 8185<br>ISO 10993 | Identical. Latest revisions are used for all applicable standards, and superseded standards have been replaced |

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| | BS EN ISO 18562-1:2024<br>BS IEC 60601-1:2020<br>BS IEC 60601-1-2:2020<br>IEC 60601-1:202005<br>IEC 60601-4-2:2016<br>IEC 62366-1:2015 +AMD1 2020 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 62366 | (ISO 80601 replacing ISO 8185) |

As evidenced by the predicate device comparison table above, the Hudson RCI® Infant Dri-Tech™ Breathing Circuits have the same characteristics as the predicate device, including intended use, operating principles, and fundamental scientific technology. The Hudson RCI® Infant 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® Infant 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 adults or patients over 32kg. The exclusion of the adult 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 neonatal, infant, and pediatric patients weighing less than 32kg.
- 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 14-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.

## 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 18562-1:2024 *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
- Volatile Organic Substances (VOCs)
- Leachables in Condensate*

The exterior circuit components are classified as intact skin contact with a Permanent contact duration (>30 days) and are identical in composition to the adult Dri-Tech versions of these components that were previously cleared under K234032.

The following biological endpoints were evaluated as part of the adult Dri-Tech submission:

- Cytotoxicity
- Irritation or Intracutaneous Reactivity
- Sensitization

In addition to the circuits, an optional ventilator accessory and extension line are available for use with the circuit. These are connected to the rear of the ventilator and are classified as Dry Gas Pathway with a Permanent contact duration (>30 days) and are cleared under K234032. See Materials section above for component classifications.

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

- Particulate matter
- Volatile Organic Substances (VOCs)

***Performance Testing (Bench)***

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| 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 |
| ISO 5367:2014 Testing<br>- Length<br>- Leakage Rate<br>- Compliance<br>- Resistance to Flow<br>- Resistance to Flow with a Bend<br>- Adaptor Retention |
| Circuit Weight Testing |
| Expiratory Star Lumen Tubing Kink and Crush Resistance |
| Moisture Removal Performance Testing |
| Dri-Tech Ventilator Accessory and Circuit Related Pressures Testing |
| 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.