May 15, 2026

Teleflex Medical Sdn. Bhd.
Suguneswary Subramaniam
Regulatory Affairs Manager - Product Management
Lot Pt. 2577
Jalan Perusahaan 4
Kamunting, Perak 34600
Malaysia

Re: K252643
Trade/Device Name: Iso-Gard Filter Straight; Humid-Vent Filter Compact Angled
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: April 15, 2026
Received: April 15, 2026

Dear Suguneswary Subramaniam:

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,

Dolly Singh Digitally signed by Dolly Singh

For Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252643

Device Name
Iso-Gard Filter Straight
Humid-Vent Filter Compact Angled

Indications for Use *(Describe)*

Iso-Gard Filter Straight:
The device is intended to remove microbiological and particulate matter from the gases in the breathing circuit.

Humid-Vent Filter Compact Angled:
The device is a combined Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care.

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.

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## K252643 510(k) Summary

**A. Name and Address of Applicant**
Teleflex Medical Sdn. Bhd.
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34600 Kamunting, Perak
Malaysia

**B. Contact Person and Phone Number**
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Regulatory Affairs Manager – Product Management
Phone: (+60) 10-221 2330

Alternate Contact:
Shah, Jigar
Senior Regulatory Affairs Manager – Product Management
Phone: (919) 503-0322

**C. Date Prepared**
May 15, 2026

**D. Device Name**
**Subject Device 1**

| | |
|---|---|
| Trade Name: | Iso-Gard Filter Straight |
| Common Name: | Filter, Bacterial, Breathing Circuit |
| Product Code: | CAH |
| Regulation Number | 21 CFR 868.5260 |
| Classification Name: | Filter, Bacterial, Breathing-Circuit |
| Classification | II |
| Classification Panel: | Anesthesia |

**Subject Device 2**

| | |
|---|---|
| Trade Name: | Humid-Vent Filter Compact Angled |
| Common Name: | Filter, Bacterial, Breathing-Circuit |
| Product Code: | CAH |
| Regulation Number | 21 CFR 868.5260 |
| Classification Name: | Filter, Bacterial, Breathing-Circuit |
| Classification | II |
| Classification Panel: | Anesthesia |

**E. Predicate Device**
K965016 Iso-Gard Filter Angled (18212)/Iso-Gard Filter Straight (19212)
K964382 Humid-Vent Filter Compact Angled (18402)/Humid-Vent Filter Compact Straight (19402)

**F. Reference Device**
K202459 Bact-Trap™ Filter, Bact-HME™ Midi HME/Filter

**G. Device Description**
The **Iso-Gard Fiter Straight** (Iso-Gard Filter S) is the device intended to remove microbiological and particulate matter from the gases in the breathing circuit. The device is intended for use in anesthesia and ventilator care for filtration of gases. The Iso-Gard Filter S is used in patients requiring filtration of breathing circuits to reduce the risk of bacterial and viral contamination.

The **Humid-Vent Filter Compact Angled** (HVF Compact A) is a combination of Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care. The HVF Compact A is for patients receiving respiratory support with dry inspired gases, where both humidification and bacterial/viral filtration are required.

Both devices were placed between the patient and breathing system are intended to replace the filtering function of nasopharynx by protecting the patient from contamination within the breathing system and reduce the risk of patients contaminating the interior of breathing systems and equipment. Additionally, HVF Compact A has the additional feature to replace warming and humidifying functions of nasopharynx.

The proposed Teleflex Medical **Iso-Gard Filter Straight** and **Humid-Vent Filter Compact Angled** are supplied as clean (non-sterile) and single use devices.

**H. Indications for Use**
**Subject Device 1 (Iso-Gard Filter Straight):**
The device is intended to remove microbiological and particulate matter from the gases in the breathing circuit.

**Subject Device 2 (Humid-Vent Filter Compact Angled):**
The device is a combined Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care.

**I. Contraindications**
**Subject Device 1 (Iso-Gard Filter Straight):**
- Patients with Excessive Airway Secretions or Bleeding: The device should not be used in patients with copious frothy secretions, significant pulmonary hemorrhage or hemoptysis, as these conditions may lead to filter blockage and increased airway resistance.
- Make sure if you use drugs with surfactant properties, that the hydrophobic pores are not blocked. This can happen if drugs are nebulized in a circuit with a cascade humidifier. Always consult with your drug manufacturer before nebulization of drugs or solutions for the first time.

**Subject Device 2 (Humid-Vent Filter Compact Angled):**

- Patients with Excessive Airway Secretions or Bleeding: The device should not be used in patients with copious frothy secretions, significant pulmonary hemorrhage or hemoptysis, as these conditions may lead to filter blockage and increased airway resistance.
- Use with External Humidification or Nebulization: The device should not be used with conventional heated humidifiers or nebulizers, as excess moisture or aerosolized medications may obstruct the filter media and compromise device function.

**J. Substantial Equivalence**

The subject devices are substantially equivalent to the predicate device with respect to intended use, technology characteristics, and construction. The differences between the predicate and the subject devices are minor and any risks have been mitigated through testing. The Reference Device (K202459) is included in this submission to provide a more recently cleared device with similar Indications for Use Technological Characteristics. The table below summarizes the differences between the subject, predicate and the reference device.

**Substantial Equivalence Comparative Table: Iso-Gard Filter Straight (Subject Device 1)**

| Features | Teleflex Medical Gibeck Iso-Gard Filter Straight (Subject Device 1, K252643) | Gibeck Iso-Gard Filter Straight (Predicate K965016) | Reference Device: Pharma System AB Bact-Trap Filter (K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **Classification Name** | Filter, Bacterial, Breathing Circuit | Filter, Bacterial, Breathing Circuit | Filter, Bacterial, Breathing Circuit | Same |
| **Product Code** | CAH | CAH | CAH | Same |
| **Regulation** | 868.5260 | 868.5260 | 868.5260 | Same |
| **Indications for Use** | The device is intended to remove microbiological and particulate matter from the gases in the breathing circuit. | Intended to remove microbiological and particulate matter from the gases in the breathing circuit. | Bact Trap filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems. The Bact Trap filter may either be used on the patient side or on the device side of the ventilator anaesthetic device. | Same |
| **Principle of Operation** | Filtration via the principle of electrostatic charges in the media. | Filtration via the principle of electrostatic charges in the media. | Filtration via the principle of electrostatic charges in the media. | Same |
| **Patient Population** | Adult and pediatric.<br>Do not use on neonate patients. | Not stated | Adult | Similar to Reference device. The subject device is having broader target population. |
| **Contraindications** | • Patients with Excessive Airway Secretions or Bleeding: The device | • Iso-Gard Filters should not be used with patients | Not stated | Similar.<br>Clarifying language added for the intended user. |

| Features | Teleflex Medical Gibeck Iso-Gard Filter Straight (Subject Device 1, K252643) | Gibeck Iso-Gard Filter Straight (Predicate K965016) | Reference Device: Pharma System AB Bact-Trap Filter (K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| | should not be used in patients with copious frothy secretions, significant pulmonary hemorrhage or hemoptysis, as these conditions may lead to filter blockage and increased airway resistance. | producing fulminating frothy secretions within their airways, or patients with hemoptysis. | | |
| | • Make sure if you use drugs with surfactant properties, that the hydrophobic pores are not blocked. This can happen if drugs are nebulized in a circuit with a cascade humidifier. Always consult with your drug manufacturer before nebulization of drugs or solutions for the first time. | • Make sure if you use drugs with surfactant properties, that the hydrophobic pores are not blocked. This can happen if drugs are nebulized in a circuit with a cascade humidifier. Always consult with your drug manufacturer before nebulization of drugs or solutions for the first time. | Not stated | Same |
| | Not applicable | • Do not use in conjunction with | Not stated | Different. Clarifying language added |

| Features | Teleflex Medical Gibeck Iso-Gard Filter Straight (Subject Device 1, K252643) | Gibeck Iso-Gard Filter Straight (Predicate K965016) | Reference Device: Pharma System AB Bact-Trap Filter (K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| | | conventional humidifiers and nebulizers.<br>• Do not add moisture to the Filter. | | for the intended user. |
| **Single Use** | Yes | Yes | Yes | Same |
| **Weight** | 23.00g | 21.7g | 32g | Different to predicate, there is a slight difference in the weight as a result of the filter media replacement. Difference to Reference device. The subject device has lighter weight when compared to the reference device. |
| **Sterile** | No | No | No | Same |
| **Lifetime/ Duration of Use** | Maximum usage duration of 24 hours | Replace every 24 hours | Intended for limited or less than 24 hours of use | Same |
| **Standard 22mm/15mm connections in compliance with ISO 5356-1** | Connectors (22M/15F–22F/15M) in compliance with ISO 5356-1 | 15/22 – 22/15mm, ISO 5356-1 | Standard conical 15mm/22mm fittings | Same |
| **Configurations** | Straight with luer port | Straight with luer port | Straight with female luer lock port | Same |
| **Component** | Upper Part/Dry Side: | Upper Part/Dry Side: | • SBC (styrene-butadiene | Same |

| Features | Teleflex Medical Gibeck Iso-Gard Filter Straight (Subject Device 1, K252643) | Gibeck Iso-Gard Filter Straight (Predicate K965016) | Reference Device: Pharma System AB Bact-Trap Filter (K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **Materials (Housing)** | Polymethyl Methacrylate Lower Part/Wet Side: Polypropylene | Polymethyl Methacrylate Lower Part/Wet Side: Polypropylene | copolymer)<br>• Polypropylene<br>• Acrylic and Polypropylene fibers<br>• Polyethylene | |
| **Component Materials (Luer Cap)** | ABS | ABS | | |
| **Component Materials (Filter Media)** | Electrostatic (Polypropylene) | Electrostatic (Polypropylene) | | Different.<br>Different grade and weightage of the filter media material for the subject device. |
| **Packaging** | Individually packed, 25 units per shelf box, 250 units per shipper carton | Individually packed, 25 units per shelf box, 250 units per shipper carton | Not stated | Same |
| **Packaging Material** | Sealed poly film/paper package | Sealed poly film/paper package | Not stated | Same |
| **General Performance** | | | | |
| **Tidal Volume (Vt)** | 250ml – 1000ml | 150ml – 1000ml | 150-1500 ml | Similar<br>(150ml – 1000ml) |
| **Filtration Efficiency per ASTM F2101** | BFE: 99.9999+%<br>VFE: 99.9967% | BFE: 99.99+%<br>VFE: 99.99% | BFE: >99.999%<br>VFE: >99.99% | Same |
| **Biocompatibility** | Materials have been tested as per<br>ISO 10993-1 and ISO 18562 | Materials have been tested as per<br>ISO 10993-1. | Materials have been tested as per<br>ISO 10993-1 and ISO 18562 | Same |

**Substantial Equivalence Comparative Table: Humid-Vent Filter Compact Angled (Subject Device 2)**

| Features | Teleflex Medical<br>Gibeck Humid-Vent Filter Compact Angled<br>(Subject Device 2, K252643) | Gibeck<br>Humid-Vent Filter Compact Angled<br>(Predicate K964382) | Reference Device:<br>Pharma System AB<br>Bact-HME Midi HME/Filter<br>(K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **Classification Name** | Filter, Bacterial, Breathing Circuit | Filter, Bacterial, Breathing Circuit | Filter, Bacterial, Breathing Circuit | Same |
| **Product Code** | CAH | CAH | CAH | Same |
| **Regulation** | 868.5260 | 868.5260 | 868.5260 | Same |
| **Indications for Use** | The device is a combined Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care. | Combined Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care. | The Bact HME/Bact-HME Midi/Pharma Mini is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The Bact HME/Bact-HME Midil Pharma Mini should be used with patients who have a Tidal Volume between 50 - 1500 ml. | Same as predicate. |

| Features | Teleflex Medical<br>Gibeck Humid-Vent Filter<br>Compact Angled<br>(Subject Device 2, K252643) | Gibeck<br>Humid-Vent Filter<br>Compact Angled<br>(Predicate K964382) | Reference Device:<br>Pharma System AB<br>Bact-HME Midi HME/Filter<br>(K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **Principle of Operation** | Filtration via the principle of electrostatic charges in the media.<br><br>Passive humidification functioning as heat and moisture exchanger to replace normal and humidify the upper airways of patient. | Filtration via the principle of electrostatic charges in the media.<br><br>Passive humidification functioning as heat and moisture exchanger to replace normal and humidify the upper airways of patient. | Filtration via the principle of electrostatic charges in the media.<br><br>Passive humidification functioning as heat and moisture exchangers. | Same |
| **Patient Population** | Adult and pediatric.<br>Do not use on neonate patients. | Not stated | Adult | Similar to Reference device. The subject device has a broader target population. |
| **Contraindications** | • Patients with Excessive Airway Secretions or Bleeding: The device should not be used in patients with copious frothy secretions, significant pulmonary hemorrhage or hemoptysis, as these conditions may lead to filter blockage and increased airway resistance. | • Humid-Vent Filter Compacts should not be used with patients producing fulminating frothy secretions within their airways, or patients with hemoptysis. | Not stated | Same |
| | • Use with External Humidification or Nebulization: The device should not be used | • Do not use in conjunction with conventional | | Same |

| Features | Teleflex Medical<br>Gibeck Humid-Vent Filter Compact Angled<br>(Subject Device 2, K252643) | Gibeck<br>Humid-Vent Filter Compact Angled<br>(Predicate K964382) | Reference Device:<br>Pharma System AB<br>Bact-HME Midi HME/Filter<br>(K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| | with conventional heated humidifiers or nebulizers, as excess moisture or aerosolized medications may obstruct the filter media and compromise device function. | humidifiers and nebulizers. | | |
| | Not applicable | • Do not add moisture to the Humid-Vent Filter Compact. | | Different.<br>Clarifying language added for the intended user. |
| **Single Use** | Yes | Yes | Yes | Same |
| **Weight** | 33.00g | 32.3g | 29.00g | Different to the predicate. A difference in the weight as a result of the filter media replacement. |
| **Sterile** | No | No | No | Same |
| **Lifetime/ Duration of Use** | Maximum usage duration of 24 hours | Replace every 24 hours | Intended for limited or less than 24 hours of use | Same |
| **Standard 22mm/15mm connections in compliance with ISO 5356-1** | Connectors (22M/15F–22F/15M) in compliance with ISO 5356-1 | 15/22 – 22/15mm, ISO 5356-1 | Standard conical 15mm/22mm fittings | Same |
| **Configurations** | Angled with luer port | Angled with luer port | Angled with female luer lock port | Same |

| Features | Teleflex Medical Gibeck Humid-Vent Filter Compact Angled (Subject Device 2, K252643) | Gibeck Humid-Vent Filter Compact Angled (Predicate K964382) | Reference Device: Pharma System AB Bact-HME Midi HME/Filter (K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **Component Materials (Housing)** | Upper Part/Dry Side: Polymethyl Methacrylate<br>Lower Part/Wet Side: Polypropylene | Upper Part/Dry Side: Polymethyl Methacrylate<br>Lower Part/Wet Side: Polypropylene | • SBC (styrene-butadiene copolymer)<br>• Polypropylene<br>• Acrylic and Polypropylene fibers<br>• Polyethylene<br>• Cross linkable acrylic polymer<br>• Silicone antifoam emulsion<br>• Polyethylene<br>• Therma11y bound Polyester (Polyethylene Terephthalate) | Same |
| **Component Materials (Luer Cap)** | ABS | ABS | | Same |
| **Component Materials (HME Media)** | Microwell paper impregnated with hygroscopic salt calcium chloride | Microwell paper impregnated with hygroscopic salt calcium chloride | | Same |
| **Component Materials (Filter Media)** | Electrostatic (Polypropylene) | Electrostatic (Polypropylene) | | Different.<br>Different grade and weightage of the filter media material for the subject device. |
| **Packaging** | Individually packed, 25 units per shelf box, 250 units per shipper carton | Individually packed, 25 units per shelf box, 250 units per shipper carton | Not stated | Same |
| **Packaging Material** | Sealed poly film/paper package | Sealed poly film/paper package | Not stated | Same |
| **General Performance** | | | | |
| **Tidal Volume (Vt)** | 150ml – 1000ml | 150ml – 1000ml | 100ml – 1200ml | Same |
| **Filtration Efficiency per** | BFE: 99.9999+%<br>VFE: 99.9979% | BFE: 99.99+%<br>VFE: 99.99% | BFE: >99.99%<br>VFE: >99.9% | Same |

| Features | Teleflex Medical<br>Gibeck Humid-Vent Filter<br>Compact Angled<br>(Subject Device 2, K252643) | Gibeck<br>Humid-Vent Filter<br>Compact Angled<br>(Predicate K964382) | Reference Device:<br>Pharma System AB<br>Bact-HME Midi HME/Filter<br>(K202459) | Comparison of Subject Device to Predicate and/or Reference Device |
|---|---|---|---|---|
| **ASTM F2101** | | | | |
| **Biocompatibility** | Materials have been tested as per ISO 10993-1 and ISO 18562 | Materials have been tested as per ISO 10993-1 | Materials have been tested as per ISO 10993-1 and ISO 18562 | Same |

**K. Comparison to the Predicate**

The table above illustrates the similarities and differences between the subject and predicate devices. The basic technological and operating principles are the same for both devices. Additionally, the indication of both subject and predicate devices are consistent, for the bacterial/viral filtration and humidification of the airway within breathing circuits. Both the subject and predicate devices are disposable, clean (non-sterile), single patient use devices. The subject devices are substantially equivalent to the predicate device.

**L. Comparison to the Reference Device**

The Reference Device (K202459) is included in this submission to provide a more recently cleared device for both the Iso-Gard Filter Straight (Subject Device 1) and the Humid-Vent Filter Compact Angled (Subject Device 2) to show that there are other devices with similar Indications and Technological Characteristics to the Subject Devices.

**M. Performance Data**

Iso-Gard Filter Straight and Humid-Vent Filter Compact Angled have undergone extensive testing to qualify it according to FDA recognized consensus standards and international standard.

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. The testing are summarize in the table below:

Subject Device 1 – Iso-Gard Filter Straight

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Performance Test** | | | |
| ISO 9360-1<br>ISO 23328-2 | Pressure Drop | Product shall be tested according to ISO 9360-1 and ISO 23328-1 to assess resistance to flow (pressure drop) across the device under specified flowrates.<br>• Vt 250ml (15 L/min)<br>• Vt 500ml (30 L/min)<br>• Vt 750ml (30 L/min)<br>• Vt 1000ml (30 L/min) | Pass |
| ISO 9360-1<br>ISO 23328-2 | Gas Leakage | Gas leakage characteristics of the breathing system filter was carried out in accordance with Clause 5.3 of ISO 23328 2, whereby the measurement of gas leakage is determined in accordance with clause 6.4 of ISO 9360 1. | Pass |
| ISO 9360-1<br>ISO 23328-2 | Dead Space | The total dead space is determined by the final weight of the product after filling with water minus the initial weight of the product before filling with water. | Pass |
| ISO 23328-1 | Salt Test | An aerosol of sodium chloride particles is generated and passed through the BSF at the specified flow rate of 15 L/min and 30 L/min. The concentrations of particles upstream and downstream of the BSF are measured, and filtration efficiency is calculated in accordance with Clause 5 of ISO 23328-1. | Pass |
| ASTM F2101 | Bacterial Filtration Efficiency (BFE) | Product shall be tested according to ASTM F2101 to assess bacterial filtration efficiency performance, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of materials. | Pass |
| | Virus Filtration Efficiency (VFE) | Product shall be tested according to ASTM F2101 to assess virus | Pass |

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Performance Test** | | | |
| | | filtration efficiency performance, employing a ratio of the upstream viral challenge to downstream residual concentration to determine filtration efficiency of materials. | |
| ISO 5356-1 | Connector Gauging Test | Leading edge lie between the minimum and maximum diameter step of the gauge. | Pass |
| ISO 80369-7<br>ISO 80369-20 | Resistance to Separation from Axial Load Test | Luer connector shall not separate from the reference connector over a hold period between 10s and 15s while being subjected to a disconnection applied axial force between 32N and 35N for Luer lock connectors. | Pass |
| | Resistance to Separation from Unscrewing Test | Luer lock shall not separate from the reference connector for a hold period between 10s and 15s while being subjected to disconnection applied axile force between 32N and 35N for Luer lock connectors. | Pass |
| | Resistance to Overriding Test | Luer lock connector shall not override the threads or lugs of the reference connector while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5s and 10s. | Pass |
| | Positive Pressure Liquid Leakage Test | Luer connector shall not show signs of leakage, sufficient to form falling drop of water, over a hold period of 30s to 35s while being subjected to an applied pressure of between 300kPa and 330kPa. | Pass |
| | Sub-atmospheric Pressure Air Leakage Test | Luer connector shall not leak by more than 0,005 Pa·m3/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15s and 20s. | Pass |
| | Stress Cracking Test | Luer connector shall meet the requirements of fluid leakage after being subjected to stress as per described in Annex E. | Pass |

Subject Device 2 – Humid-Vent Filter Compact Angled

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Performance Test** | | | |
| ISO 9360-1 | Moisture Loss | Product shall be tested according to ISO 9360-1 to assess moisture loss, whereby the mass of water lost from the test apparatus is recorded. | Pass |
| ISO 9360-1<br>ISO 23328-2 | Pressure Drop | Product shall be tested according to ISO 9360-1 and ISO 23328-1 to assess resistance to flow (pressure drop) across the device under specified flowrates.<br>• Vt 150ml (15 L/min, 30 L/min, 60 L/min, 90 L/min)<br>• Vt 250ml (15 L/min, 30 L/min, 60 L/min, 90 L/min)<br>• Vt 500ml (15 L/min, 30 L/min, 60 L/min, 90 L/min)<br>• Vt 750ml (15 L/min, 30 L/min, 60 L/min, 90 L/min)<br>• Vt 1000ml (15 L/min, 30 L/min, 60 L/min, 90 L/min) | Pass |
| ISO 9360-1<br>ISO 23328-2 | Gas Leakage | Gas leakage characteristics of the breathing system filter was carried out in accordance with Clause 5.3 of ISO 23328 2, whereby the measurement of gas leakage is determined in accordance with clause 6.4 of ISO 9360 1. | Pass |
| ISO 9360-1 | Compliance | Product shall be tested according to ISO 9360-1 to assess compliance. | Pass |
| ISO 9360-1<br>ISO 23328-2 | Dead Space | The total dead space is determined by the final weight of the product after filling with water minus the initial weight of the product before filling with water. | Pass |
| ISO 23328-1 | Salt Test | An aerosol of sodium chloride particles is generated and passed through the BSF at the specified flow rate of 15L/min and 30 L/min. The concentrations of particles upstream and downstream of the BSF are | Pass |

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Performance Test** | | | |
| | | measured, and filtration efficiency is calculated in accordance with Clause 5 of ISO 23328-1. | |
| ASTM F2101 | Bacterial Filtration Efficiency (BFE) | Product shall be tested according to ASTM F2101 to assess bacterial filtration efficiency performance, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of materials. | Pass |
| | Virus Filtration Efficiency (VFE) | Product shall be tested according to ASTM F2101 to assess virus filtration efficiency performance, employing a ratio of the upstream viral challenge to downstream residual concentration to determine filtration efficiency of materials. | Pass |
| ISO 5356-1 | Connector Gauging Test | Leading edge lie between the minimum and maximum diameter step of the gauge. | Pass |
| ISO 80369-7<br>ISO 80369-20 | Resistance to Separation from Axial Load Test | Luer connector shall not separate from the reference connector over a hold period between 10s and 15s while being subjected to a disconnection applied axial force between 32N and 35N for Luer lock connectors. | Pass |
| | Resistance to Separation from Unscrewing Test | Luer lock shall not separate from the reference connector for a hold period between 10s and 15s while being subjected to disconnection applied axile force between 32N and 35N for Luer lock connectors. | Pass |
| | Resistance to Overriding Test | Luer lock connector shall not override the threads or lugs of the reference connector while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5s and 10s. | Pass |
| | Positive Pressure Liquid Leakage Test | Luer connector shall not show signs of leakage, sufficient to form falling drop of water, over | Pass |

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Performance Test** | | | |
| | | a hold period of 30s to 35s while being subjected to an applied pressure of between 300kPa and 330kPa. | |
| | Sub-atmospheric Pressure Air Leakage Test | Luer connector shall not leak by more than 0,005 Pa·m3/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15s and 20s. | Pass |
| | Stress Cracking Test | Luer connector shall meet the requirements of fluid leakage after being subjected to stress as per described in Annex E. | Pass |

Biological testing was performed according to the requirements of ISO 10993-1 Fifth Edition 2018-08 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, and ISO 18562-1 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 1: Evaluation and Testing within a Risk Management Process. The testing are summarize in the table below:

Subject Device 1 – Iso-Gard Filter Straight

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Biocompatibility Test** | | | |
| ISO 10993-5 | Cytotoxicity | Assess whether the final and completed device emits any harmful substances. This evaluation conducted using an in vitro assay on mouse fibroblast (L929) cells. Reactivity scores greater than 2 indicate cytotoxicity for the device. | Pass |
| ISO 10993-10 | Sensitization | Determine if the extracts of the test article trigger an immune response that results in an allergic reaction. Consider a device sensitizing if it scores ≥1 according to Magnusson and Kligman grading scale. | Pass |
| ISO 10993-23 | Intracutaneous Irritation | Determine if the device produces a local irritation response in the dermal tissues. This in vivo assay is carried out on three rabbits. Device is classified as an irritant if the comparative result. Average score of the test animals minus that of the control animals, is greater than 1. | Pass |
| ISO 10993-11<br>ISO 10993-12 | Acute Systemic Toxicity | The endpoints were evaluated through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 10993-3 | Genotoxicity | Evaluation through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 10993-11 | Subacute Toxicity | Evaluation through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 18562-2<br>ISO 18562-3 | Particulate Matter<br>Volatile Organic Substance<br>Toxicology Risk Assessment | Particulate and VOC testing followed by toxicological risk assessment is to determine whether VOC and particulate exposure from the device produces toxicological risk per ISO 10993-17. Testing and evaluation is considered acceptable if the toxicological risk assessment concludes that "All the chemical exposures below the conservative TSL ≤30 d of 120µg, TTC of 120µg/day, or derived TIs". | Pass |
| ISO 18562-4 | Leachable in Condensate | Chemical characterization followed by toxicological risk assessment is to determine whether extractable and | Pass |

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| | Toxicological Risk Assessment | leachables exposure from the device produce toxicological risk per ISO 10993-17. Testing and evaluation is considered acceptable if the toxicological risk assessment concludes that "All the chemical exposures below the conservative TSL ≤30 d of 120µg, TTC of 120µg/day, or derived TIs". | |

Subject Device 2 – Humid-Vent Filter Compact Angled

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| **Biocompatibility Test** | | | |
| ISO 10993-5 | Cytotoxicity | Assess whether the final and completed device emits any harmful substances. This evaluation conducted using an in vitro assay on mouse fibroblast (L929) cells. Reactivity scores greater than 2 indicate cytotoxicity for the device. | Pass |
| ISO 10993-10 | Sensitization | Determine if the extracts of the test article trigger an immune response that results in an allergic reaction. Consider a device sensitizing if it scores ≥1 according to Magnusson and Kligman grading scale. | Pass |
| ISO 10993-23 | Intracutaneous Irritation | Determine if the device produces a local irritation response in the dermal tissues. This in vivo assay is carried out on three rabbits. Device is classified as an irritant if the comparative result. Average score of the test animals minus that of the control animals, is greater than 1. | Pass |
| ISO 10993-11<br>ISO 10993-12 | Acute Systemic Toxicity | The endpoints were evaluated through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 10993-3 | Genotoxicity | Evaluation through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 10993-11 | Subacute Toxicity | Evaluation through the process of chemical characterization and toxicological risk assessment. | Pass |
| ISO 18562-2<br><br>ISO 18562-3 | Particulate Matter<br><br>Volatile Organic Substance<br><br>Toxicology Risk Assessment | Particulate and VOC testing followed by toxicological risk assessment is to determine whether VOC and particulate exposure from the device produces toxicological risk per ISO 10993-17. Testing and evaluation is considered acceptable if the toxicological risk assessment concludes that "All the chemical exposures below the conservative TSL ≤30 d of 120µg, TTC of 120µg/day, or derived TIs". | Pass |
| ISO 18562-4 | Leachable in Condensate | Chemical characterization followed by toxicological risk assessment is to determine whether extractable and | Pass |

| Test Standard | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| | Toxicological Risk Assessment | leachables exposure from the device produce toxicological risk per ISO 10993-17. Testing and evaluation is considered acceptable if the toxicological risk assessment concludes that "All the chemical exposures below the conservative TSL ≤30 d of 120µg, TTC of 120µg/day, or derived TIs". | |

## N. Conclusion

The subject device has the same indications for use and technological characteristics and construction as the predicate. Test results demonstrate that the subject device meets its intended use. It is for these reasons that the subject device can be found substantially equivalent to the predicate devices.

The reference device, which has similar indications and technological characteristics, provides a reference to a more recently cleared device.

The conclusion drawn from the non-clinical performance test demonstrate that the device (Iso-Gard Filter Straight and Humid-Vent Filter Compact Angled) is substantially equivalent to the legally marketed device.