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**Non-confidential**  
**510(k) Summary of Safety and Effectiveness**

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**Device name**

Trade or proprietary name: Cat. No. 1605 Bacteria / Viral Filter  
Classification name: Breathing Circuit Bacterial Filter  
Common or usual name: breathing filter

**Predicate device**

Gibeck product no. 1910 Iso-Gard Depth Filter, also known as the Dryden II Filter K# 792097

**Device description**

The Hudson RCI Cat. No. 1605 Bacteria / Viral Filter is a disposable, single patient use breathing filter consisting of a gas-permeable filter medium captured between two clear plastic housings. When the Hudson RCI Cat. No. 1605 Bacteria / Viral Filter is inserted into a breathing circuit, the respiratory gas passes through the electrostatically-charged hydrophobic filter medium within the filter. The medium traps bacteria and viruses carried within the airstream.

**Intended use**

For use on all patient populations, in conjunction with other respiratory devices containing standard 15 mm and/or 22 mm fittings (such as breathing circuits and the like) to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

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**Technological Comparison**

Both the Hudson RCI Bacteria/Viral Filter and the Gibeck filter have similar intended uses and clinical applications. Both devices are intended for use in all patient populations requiring ventilatory support or supplemental oxygen where infection from airborne bacteria or viruses is of concern. Both devices are intended for use in conjunction with other respiratory devices containing standard 15mm and/or 22mm fittings (such as breathing circuits and the like). Neither device is intended for direct contact with the patient, nor does either of the devices use or impart energy. Both devices utilize a similar method of operation in that gas passes through a filter medium which traps bacteria and viruses carried within the airstream.

Both the Hudson RCI Bacteria/Viral Filter and the Gibeck filter utilize similar gas permeable hydrophobic media for the filters. The Hudson RCI filter features a circular/spherical housing, while the Gibeck filter utilizes a squared housing. Both devices feature a design which possess ISO 22mm ID and ISO 22mm OD/15mm ID connectors. The Hudson RCI Bacteria/Viral filter may be offered with an optional gas sampling port. The Gibeck filter does not offer this feature. The addition of a gas sampling port would allow the practitioner to monitor exhaled gases while protecting the gas monitoring equipment from bacterial or viral contamination.

The Hudson RCI Bacteria/Viral Filter and the Gibeck filter have been tested by an independent laboratory for bacterial and viral filtration performance. Both filters displayed a bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) of greater than 99.9%, with the Hudson RCI filter displaying a BFE of 99.999% and a VFE of 99.99%. A dead space test was performed on both the Hudson RCI and Gibeck filters. The Hudson RCI filter possesses a dead space of 42mL, while the Gibeck filter possesses a dead space of 35mL. Although the dead space for the Hudson RCI filter is slightly greater than that of the Gibeck filter, the clinician compensates for dead space during ventilatory set-up.

**Conclusion**

Based upon comparison to the identified predicate device and the results of the testing performed, Hudson RCI concludes that the Hudson RCI Bacteria/Viral filter is safe and effective and performs as well or better than the Gibeck Iso-Gard Filter.

