



MAY - 2 1996

K954828

Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck Iso-Gard[®] HEPA Filter-HME and
Iso-Gard[®] HEPA Filter-HME with Port

Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are combination products, i.e. bacterial/viral filters and heat and moisture exchangers, and are substantially equivalent to the Humid-Vent Filter. The bacterial filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.0 microns. The viral filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.1 microns. The moisture output has been demonstrated to be 26.6 mg H₂O/l air at 300 ml tidal volume and 22.2 mg H₂O/l air at 600 ml tidal volume.

The principal differences between the Iso-Gard HEPA Filter-HME, the Iso-Gard HEPA Filter-HME with Port and the Humid-Vent Filter are the design of the housing and the filtration/HME media utilized. These differences are not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should these differences significantly affect the safety or effectiveness of the device when used as labeled.



Submitter/Contact Person

2/9/96
Date