

K954828 ISO-GARD HEPA FILTER-HME, ISO-ARD HEPA FILTER-HME W/PORTMay 2, 1996
195 days to decisionK954828 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k954828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Oct 20, 1995
Decision date	May 2, 1996
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gibeck, Inc.
Location	Indianapolis, IN, US
Contact	BRIAN GRIGSBY
510(k) history	15 submissions · 15 cleared · 1990-1997

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