

K965016 ISO-GARD FILTER ANGLED(18212)/ISO-GARD FILTER STRAIGHT(19212)Dec 2, 1997
351 days to decisionK965016 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k965016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Dec 16, 1996
Decision date	Dec 2, 1997
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k965016/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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