

K132679 AF VIRAL/BACTERIAL FILTER, BF VIRAL/BACTERIAL FILTERApr 18, 2014
233 days to decisionK132679 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k132679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Aug 28, 2013
Decision date	Apr 18, 2014
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Galemed Corp.
Location	Temecula, CA, US
Contact	TOM SHANKS
510(k) history	7 submissions · 7 cleared · 2002-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132679/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026