

K163300 ThermoShield HME FilterMar 22, 2017
120 days to decisionK163300 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k163300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Nov 22, 2016
Decision date	Mar 22, 2017
Days to decision	120 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Flexicare Medical Limited.
Location	Mountain Ash, GB
Contact	Joel Biddle
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163300/> 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