

**K191909 HepaShield Bacterial Viral Breathing System Filter**Mar 23, 2020  
250 days to decisionK191909 · Product code: **CAH** · General Hospital  
Source: <https://www.510kdatabase.net/k191909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Jul 17, 2019
Decision date	Mar 23, 2020
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191909/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026