

**K021265 DATEX-OHMEDA HMEF 500**Aug 30, 2002  
130 days to decisionK021265 · Product code: **CAH** · General Hospital  
Source: <https://www.510kdatabase.net/k021265/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Apr 22, 2002
Decision date	Aug 30, 2002
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datex-Ohmeda</b>
Location	Tewksbury, MA, US
Contact	JOEL C KENT
510(k) history	41 submissions · 41 cleared · 2000-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021265/> 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