

**K882799 HELENA COLOCARE**Sep 30, 1988  
86 days to decisionK882799 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k882799/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Jul 6, 1988
Decision date	Sep 30, 1988
Days to decision	86 days
Third-party review	No

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	ERIC PETERSEN
510(k) history	280 submissions · 280 cleared · 1978-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k882799/>; 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 14, 2026