

**K052598 IMMO CARE**Mar 16, 2006  
176 days to decisionK052598 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k052598/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Sep 21, 2005
Decision date	Mar 16, 2006
Days to decision	176 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Care Diagnostic, Inc.</b>
Location	Klamath Falls, OR, US
Contact	ARACELI FANCHER-FERREIRA
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052598/> 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 June 28, 2026