

**K060930 INSURE II**May 4, 2006  
29 days to decisionK060930 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k060930/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagent, Occult Blood (KHE)
Date received	Apr 5, 2006
Decision date	May 4, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Enterix, Inc.</b>
Location	Falmouth,, ME, US
Contact	EDWIN DIAZ
510(k) history	3 submissions · 3 cleared · 2001-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060930/> 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 31, 2026