

**K881907 HEMAGEL(TM) TEST FOR FECAL OCCULT BLOOD**Jul 8, 1988  
63 days to decisionK881907 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k881907/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	May 6, 1988
Decision date	Jul 8, 1988
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>Enzo Biochem, Inc.</b>
Location	New York, NY, US
Contact	J OLSIEWSKI
510(k) history	5 submissions · 5 cleared · 1987-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881907/>; 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 29, 2026