

**K961062 FLEXSURE OBТ**Nov 6, 1996  
233 days to decisionK961062 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k961062/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Mar 18, 1996
Decision date	Nov 6, 1996
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smithkline Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	MARSHALL C MCCARTY
510(k) history	42 submissions · 42 cleared · 1976-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961062/> 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