

K913622 HEMOPLUSJan 31, 1992
170 days to decisionK913622 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k913622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Aug 14, 1991
Decision date	Jan 31, 1992
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sarstedt, Inc.
Location	Newton, NC, US
Contact	JAMES E YANCSEK
510(k) history	6 submissions · 6 cleared · 1992-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913622/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026