

K981661 HEMAPROMPTSep 15, 1998
132 days to decisionK981661 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k981661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	May 6, 1998
Decision date	Sep 15, 1998
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aerscher Diagnostics
Location	Chestertown, MD, US
Contact	ROBERT SCHREIBER
510(k) history	3 submissions · 3 cleared · 1997-2003

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