

K031356 HEMAPROMPT GASTRICSep 24, 2003
166 days to decisionK031356 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k031356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Apr 11, 2003
Decision date	Sep 24, 2003
Days to decision	166 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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