

K980671 COLOSCREEN-ESMay 12, 1998
81 days to decisionK980671 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k980671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Feb 20, 1998
Decision date	May 12, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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