

K911075 COLOSCREENJul 3, 1991
114 days to decisionK911075 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k911075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Mar 11, 1991
Decision date	Jul 3, 1991
Days to decision	114 days
Third-party review	No

APPLICANT

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

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