

K812428 HELENA COLOSCREEN METHODOct 23, 1981
59 days to decisionK812428 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k812428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Aug 25, 1981
Decision date	Oct 23, 1981
Days to decision	59 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k812428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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