

**K843352 COLOSCREEN SELF-TEST**Dec 5, 1984  
100 days to decisionK843352 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k843352/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Aug 27, 1984
Decision date	Dec 5, 1984
Days to decision	100 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843352/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026