

K834456 HELENA BIO STRIP OBJan 13, 1984
25 days to decisionK834456 · Product code: **KHE** · Chemistry
Source: <https://www.510kdatabase.net/k834456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Dec 19, 1983
Decision date	Jan 13, 1984
Days to decision	25 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k834456/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026