

K896474 RESUBMITTED FECATWIN SENSITIVE - FECA-EIAJan 25, 1990
73 days to decisionK896474 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k896474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Nov 13, 1989
Decision date	Jan 25, 1990
Days to decision	73 days
Third-party review	No

APPLICANT

Company	Labsystems, Inc.
Location	Walker, MI, US
Contact	PAIVI SORMUNEN
510(k) history	17 submissions · 17 cleared · 1984-1993

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