

K935162 REP DIRECT-SEP CHOLESTEROL-15 KITNov 10, 1994
377 days to decisionK935162 · Product code: **JHO** · Chemistry
Source: <https://www.510kdatabase.net/k935162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Lipoproteins (JHO)
Date received	Oct 29, 1993
Decision date	Nov 10, 1994
Days to decision	377 days
Third-party review	No
Summary / Statement	Statement
Other names	CHOLESTEROL-8 KIT; CHOLESTEROL-4 KIT

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k935162/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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