

K932442 CARDIO REP RECOMBINANT CK ABNORMAL CONTROLOct 28, 1993
161 days to decisionK932442 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k932442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	May 20, 1993
Decision date	Oct 28, 1993
Days to decision	161 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k932442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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