

K950801 CARDIO REP LD CONTROL - CAT NO. 3325Mar 30, 1995
37 days to decisionK950801 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k950801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Feb 21, 1995
Decision date	Mar 30, 1995
Days to decision	37 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

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