

K931050 CARDIO REP CK ISOENZYME KIT - 3310Apr 20, 1993
50 days to decisionK931050 · Product code: **JHW** · Chemistry
Source: <https://www.510kdatabase.net/k931050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Method, Cpk Isoenzymes (JHW)
Date received	Mar 1, 1993
Decision date	Apr 20, 1993
Days to decision	50 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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