

**K932768 CARDIO REP CK CALIBRATORS 1 & 2 CAT. NO. 3322  
& 3323**Oct 18, 1993  
132 days to decisionK932768 · Product code: JIX · Chemistry  
Source: <https://www.510kdatabase.net/k932768/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Jun 8, 1993
Decision date	Oct 18, 1993
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932768/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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