

**K944243 CARDIOCHEX**Oct 27, 1994  
57 days to decisionK944243 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k944243/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Aug 31, 1994
Decision date	Oct 27, 1994
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cala Diagnostics</b>
Location	Los Osos, CA, US
Contact	JAMES F GODFREY
510(k) history	12 submissions · 12 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944243/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026