

K944246 CARDIOCHEX CKMB MASS MEASUREMENT CONTROLOct 31, 1994
61 days to decisionK944246 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k944246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Aug 31, 1994
Decision date	Oct 31, 1994
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944246/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026