

**K032089 ROCHE DIAGNOSTICS ELECSYS PRECICONTROL
CARDIAC**Jul 30, 2003
23 days to decisionK032089 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k032089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jul 7, 2003
Decision date	Jul 30, 2003
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	SHERRI L COENEN
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032089/> 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 9, 2026