

**K062972 PRECINORM CK-MB AND PRECIPATH CK-MB
CONTROLS**Oct 13, 2006
14 days to decisionK062972 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k062972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 29, 2006
Decision date	Oct 13, 2006
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062972/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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