

K897097 COBAS READY CALIBRATOR KITJun 26, 1990
187 days to decisionK897097 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k897097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 21, 1989
Decision date	Jun 26, 1990
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

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