

K897071 ROCHE STANDARDS FOR THE COBAS ISE MODULEMar 9, 1990
77 days to decisionK897071 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k897071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 22, 1989
Decision date	Mar 9, 1990
Days to decision	77 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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Device record: <https://www.510kdatabase.net/k897071/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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