

K952282 ROCHE AMMONIA/ETHANOL/CO2 CALIBRATORSep 15, 1995
122 days to decisionK952282 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k952282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	May 16, 1995
Decision date	Sep 15, 1995
Days to decision	122 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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