

K990460 CALIBRATOR FOR AUTOMATED SYSTEMS (C.F.A.S.)Mar 22, 1999
38 days to decisionK990460 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k990460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Feb 12, 1999
Decision date	Mar 22, 1999
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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