

K011226 CALIBRATOR FOR AUTOMATED SYSTEMSJun 25, 2001
66 days to decisionK011226 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k011226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Apr 20, 2001
Decision date	Jun 25, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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