

K925385 REAGENTS FOR ABBOTT SPECTRUM/EPX (ELECTRO CALIBRA)Jan 13, 1994
444 days to decisionK925385 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k925385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Oct 26, 1992
Decision date	Jan 13, 1994
Days to decision	444 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alko Diagnostic Corp.
Location	Mchenry, IL, US
Contact	BRIAN J YOUNG
510(k) history	31 submissions · 31 cleared · 1982-2000

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