

K970921 STANDARD A MULTIPLY (A540-0), STANDARD B MULTIPLY (A550-0), STANDARD C MULTIPLY (A560-0)

Apr 8, 1997
27 days to decision

K970921 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k970921/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Mar 12, 1997
Decision date	Apr 8, 1997
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alko Diagnostic Corp.
Location	Mchenry, IL, US
Contact	JANET A MCGRATH
510(k) history	31 submissions · 31 cleared · 1982-2000

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Device record: <https://www.510kdatabase.net/k970921/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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