FDA 510(k) Premarket Notification

K925101 SYSTEMATE PLUS CALIBRATOR

CLEARED

Feb 23, 1993
138 days to decision

K925101 · Product code: **JIX** · Chemistry
Source: https://www.510kdatabase.net/k925101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Oct 8, 1992
Decision date	Feb 23, 1993
Days to decision	138 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Em Diagnostic Systems, Inc.**
Location	Walker, MI, US
Contact	ANNA G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k925101/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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