FDA 510(k) Premarket Notification

K970778 LEAD CONTROL (WHOLE BLOOD) LEVELS 1,2,3,4

CLEARED

Apr 17, 1997
44 days to decision

K970778 · Product code: **JJX** · Chemistry
Source: https://www.510kdatabase.net/k970778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 4, 1997
Decision date	Apr 17, 1997
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**More Diagnostics**
Location	Los Osos, CA, US
Contact	JAMES W SNIPES
510(k) history	16 submissions · 16 cleared · 1993-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k970778/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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