

K945337 PHENYTOIN CALIBRATORSDec 7, 1994
36 days to decisionK945337 · Product code: **DLJ** · Toxicology
Source: <https://www.510kdatabase.net/k945337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Nov 1, 1994
Decision date	Dec 7, 1994
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUG-GEN TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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