

K945316 PHENOBARBITAL CALIBRATORSJan 4, 1995
64 days to decisionK945316 · Product code: **DLJ** · Toxicology
Source: <https://www.510kdatabase.net/k945316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Nov 1, 1994
Decision date	Jan 4, 1995
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026