

**K935101 URINE CALIBRATORS AND CONTROLS
MODIFICATION**Jan 27, 1994
99 days to decisionK935101 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k935101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Oct 20, 1993
Decision date	Jan 27, 1994
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935101/> 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