

K002331 PROFILE-ERJan 17, 2001
169 days to decisionK002331 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k002331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Aug 1, 2000
Decision date	Jan 17, 2001
Days to decision	169 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medtox Diagnostics, Inc.
Location	Burlington, NC, US
Contact	MICHAEL TURANCHIK
510(k) history	22 submissions · 22 cleared · 1998-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002331/> 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