FDA 510(k) Premarket Notification

K002331 PROFILE-ER

CLEARED

Jan 17, 2001
169 days to decision

K002331 · 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