

**K010138 PROFILE II ER**Feb 14, 2001  
28 days to decisionK010138 · Product code: **LDJ** · Toxicology  
Source: <https://www.510kdatabase.net/k010138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Jan 17, 2001
Decision date	Feb 14, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010138/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026