

K010564 VERDICT -II THC/COC/OPI/AMP/PCP/BAR/BZO & THC/COC/BAR/BZOApr 5, 2001
38 days to decisionK010564 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k010564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 26, 2001
Decision date	Apr 5, 2001
Days to decision	38 days
Third-party review	No
Summary / Statement	Statement
Other names	PROFILE -II 7 THC/COC/OPI/AMP/PCP/BAR/BZO

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/k010564/> 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