

**K000460 URINE AMPHETAMINE/METHAMPHETAMINE (AMPH)
SCREEN FLEX REAGENT, CATALOG NO. DF 90A**

Apr 14, 2000
63 days to decision

K000460 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k000460/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 11, 2000
Decision date	Apr 14, 2000
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	JUDY MCINNIS-BERGER
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000460/> 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 19, 2026