

K043028 EMIT II PLUS ECSTASY ASSAYJan 7, 2005
65 days to decisionK043028 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k043028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Nov 3, 2004
Decision date	Jan 7, 2005
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	YUK-TING LEWIS
510(k) history	343 submissions · 343 cleared · 1978-2010

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