

**K012257 EMIT II PLUS MONOCLONAL
AMPHETAMINE/METHAMPHETAMINE ASSAY MODEL
OSR9C229**Aug 3, 2001
16 days to decisionK012257 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k012257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jul 18, 2001
Decision date	Aug 3, 2001
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	SUSAN L COLLINS
510(k) history	448 submissions · 447 cleared · 1976-2001

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