

**K955935 TRIAGE PANEL FOR DRUGS OF ABUSE/TRICYCLIC
ANTIDEPRESSANTS**Feb 15, 1996
64 days to decisionK955935 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k955935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 13, 1995
Decision date	Feb 15, 1996
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biosite Incorporated
Location	San Diego, CA, US
Contact	JOHN F BRUNI
510(k) history	46 submissions · 45 cleared · 1990-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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