

**K012745 TRIAGE TOX DRUG SCREEN, CATALOG #94000**Jan 10, 2002  
147 days to decisionK012745 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k012745/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Aug 16, 2001
Decision date	Jan 10, 2002
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biosite Incorporated</b>
Location	San Diego, CA, US
Contact	JEFFREY R DAHLEN
510(k) history	46 submissions · 45 cleared · 1990-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012745/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026