

**K093114 THERMO SCIENTIFIC DRI AMPHETAMINES ASSAY**May 12, 2010  
223 days to decisionK093114 · Product code: **DKZ** · Chemistry  
Source: <https://www.510kdatabase.net/k093114/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Oct 1, 2009
Decision date	May 12, 2010
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Microgenics Corp.</b>
Location	Concord, CA, US
Contact	HEWUAN TAKKELE
510(k) history	107 submissions · 106 cleared · 1985-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093114/> 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