

K012109 DRI ECSTASY URINE CALIBRATORSAug 27, 2001
52 days to decisionK012109 · Product code: **DLJ** · Toxicology
Source: <https://www.510kdatabase.net/k012109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Jul 6, 2001
Decision date	Aug 27, 2001
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corp.
Location	Concord, CA, US
Contact	SHERRIE RINNE
510(k) history	107 submissions · 106 cleared · 1985-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012109/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026