

K101745 THERMO SCIENTIFIC CEDIA AMPHETAMINE OFT ASSAYApr 8, 2011
290 days to decisionK101745 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k101745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jun 22, 2010
Decision date	Apr 8, 2011
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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