

K945345 CEDIA DAU COCAINE ASSAYJan 17, 1995
77 days to decisionK945345 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k945345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Nov 1, 1994
Decision date	Jan 17, 1995
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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