

K941195 CEDIA DAU OPIATE ASSAYSep 7, 1994
177 days to decisionK941195 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k941195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 14, 1994
Decision date	Sep 7, 1994
Days to decision	177 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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