

**K040316 CEDIA BUPRENORPHINE ASSAY**Jun 23, 2004  
135 days to decisionK040316 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k040316/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Feb 9, 2004
Decision date	Jun 23, 2004
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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