

**K173183 CEDIA Heroin Metabolite (6-AM) Assay**Nov 22, 2017  
51 days to decisionK173183 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k173183/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 2, 2017
Decision date	Nov 22, 2017
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microgenics Corporation</b>
Location	Fremont Blvd., CA, US
Contact	Minoti Patel
510(k) history	21 submissions · 20 cleared · 2009-2024

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