

**K181499 DRI Cocaine Metabolite Assay**Jul 6, 2018  
29 days to decisionK181499 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k181499/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 7, 2018
Decision date	Jul 6, 2018
Days to decision	29 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	Emily Chien
510(k) history	21 submissions · 20 cleared · 2009-2024

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