

K211973 DRI Cocaine Metabolite AssaySep 24, 2021
91 days to decisionK211973 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k211973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 25, 2021
Decision date	Sep 24, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corporation
Location	Fremont Blvd., CA, US
Contact	Nikhita Tandon
510(k) history	21 submissions · 20 cleared · 2009-2024

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