

K191638 Pointe Scientific Cocaine Metabolite Enzyme ImmunoassayMar 12, 2020
267 days to decisionK191638 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k191638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 19, 2019
Decision date	Mar 12, 2020
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtest DX
Location	Lincoln Park, MI, US
Contact	William Cripps
510(k) history	2 submissions · 2 cleared · 2020-2020

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