

K053422 RAPIDONE-COCAINE-150 TESTJun 15, 2006
189 days to decisionK053422 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k053422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Dec 8, 2005
Decision date	Jun 15, 2006
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Bio Medica Corp.
Location	Washington, DC, US
Contact	HENRY WELLS
510(k) history	30 submissions · 30 cleared · 1997-2017

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