

**K964900 RAPID DRUG SCREEN**Apr 14, 1997  
138 days to decisionK964900 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k964900/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Nov 27, 1996
Decision date	Apr 14, 1997
Days to decision	138 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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