

K990822 RAPIDONE - COCAINE TESTJul 15, 1999
126 days to decisionK990822 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k990822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Mar 11, 1999
Decision date	Jul 15, 1999
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990822/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026