

K921834 AUTOMATES COMA COCAINE METABOLITE ASSAYJun 15, 1992
60 days to decisionK921834 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k921834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 16, 1992
Decision date	Jun 15, 1992
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Serex, Inc.
Location	Englewood, NJ, US
Contact	VICTOR LEE-OWN
510(k) history	5 submissions · 5 cleared · 1989-1992

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