

**K895043 COMA COCAINE METABOLITE ASSAY (EIA)**Nov 8, 1989  
91 days to decisionK895043 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k895043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Aug 9, 1989
Decision date	Nov 8, 1989
Days to decision	91 days
Third-party review	No

**APPLICANT**

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Company	<b>Serex, Inc.</b>
Location	Englewood, NJ, US
Contact	FITZPATRICK-DAVIS
510(k) history	5 submissions · 5 cleared · 1989-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895043/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026