

**K011162 MODIFICATION TO THE EMIT II PLUS COCAINE  
METABOLITE ASSAY**May 2, 2001  
16 days to decisionK011162 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k011162/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 16, 2001
Decision date	May 2, 2001
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syva Co., Dade Behring, Inc.</b>
Location	San Jose, CA, US
Contact	SUSAN COLLINS
510(k) history	19 submissions · 19 cleared · 2000-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011162/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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