

K031512 EMIT II PLUS COCAINE METABOLITE ASSAYJul 23, 2003
70 days to decisionK031512 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k031512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	May 14, 2003
Decision date	Jul 23, 2003
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN A DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

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