

K935016 COCAINE METABOLITE EIA ASSAY MODIFICATIONDec 3, 1993
46 days to decisionK935016 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k935016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 18, 1993
Decision date	Dec 3, 1993
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YEH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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