

K963918 IMMULITE COCAINE METABOLITEApr 8, 1997
190 days to decisionK963918 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k963918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Sep 30, 1996
Decision date	Apr 8, 1997
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE, PH.D.
510(k) history	321 submissions · 321 cleared · 1976-2006

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