

K050465 IMMUNALYSIS COCAINE ELISA FOR HAIRAug 4, 2005
154 days to decisionK050465 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k050465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Mar 3, 2005
Decision date	Aug 4, 2005
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immunalysis Corporation
Location	Mchenry, IL, US
Contact	MICHAEL VINCENT
510(k) history	50 submissions · 50 cleared · 1978-2025

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