

**K051578 IMMUNALYSIS COCAINE/COCAINE METABOLITE
ELISA FOR ORAL FLUIDS**Nov 18, 2005
157 days to decisionK051578 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k051578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 14, 2005
Decision date	Nov 18, 2005
Days to decision	157 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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