

K150925 Immunoassay Benzoyllecgonine Urine Enzyme Immunoassay, Immunoassay Benzoyllecgonine Urine Calibrators, Immunoassay Benzoyllecgonine Urine Control SetJun 29, 2015
84 days to decisionK150925 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k150925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 6, 2015
Decision date	Jun 29, 2015
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Immunoassay Corporation
Location	Mchenry, IL, US
Contact	Joseph Ginete
510(k) history	50 submissions · 50 cleared · 1978-2025

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