

**K151395 Immunalysis EDDP Specific Urine Enzyme
Immunoassay, Immunalysis EDDP Urine Calibrators,
Immunalysis EDDP Urine Control Sets**Jul 24, 2015
59 days to decisionK151395 · Product code: **DJR** · Toxicology
Source: <https://www.510kdatabase.net/k151395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	May 26, 2015
Decision date	Jul 24, 2015
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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