

K913863 URINE HEROIN/MORPHINE DIRECT RIA KIT (I-125)Sep 19, 1991
23 days to decisionK913863 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k913863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 27, 1991
Decision date	Sep 19, 1991
Days to decision	23 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913863/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026