

K913867 URINE COCAINE METABOLITE DIRECT RIA KIT (I-125)Sep 19, 1991
23 days to decisionK913867 · Product code: **KLN** · Toxicology
Source: <https://www.510kdatabase.net/k913867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Cocaine Metabolite (KLN)
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/k913867/> 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