

K912754 ABUSCREEN RADIOIMMUNOASSAY FOR METHAMPHETAMINESep 27, 1991
98 days to decisionK912754 · Product code: **DPJ** · Toxicology
Source: <https://www.510kdatabase.net/k912754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Amphetamine (125-i), Goat Antibody, Ammonium Sulfate Sep. (DPJ)
Date received	Jun 21, 1991
Decision date	Sep 27, 1991
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	CAROL KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912754/> 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 23, 2026