

**K935055 ROCHE ABUSCREEN RADIOIMMUNOASSAY FOR MORPHINE (HIGH CUT-OFF)**Aug 9, 1994  
293 days to decisionK935055 · Product code: **DOE** · Toxicology  
Source: <https://www.510kdatabase.net/k935055/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Morphine (125-i), Goat Antibody Ammonium Sulfate Sep. (DOE)
Date received	Oct 20, 1993
Decision date	Aug 9, 1994
Days to decision	293 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935055/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026