

**K964355 ONTRAK TESTCUP 5 (MODIFICATION)**Dec 13, 1996  
42 days to decisionK964355 · Product code: **LCM** · Toxicology  
Source: <https://www.510kdatabase.net/k964355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Nov 1, 1996
Decision date	Dec 13, 1996
Days to decision	42 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	ALEX WESOLOWSKI
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/k964355/> 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