

**K964422 ONTRAK TESTTCUP COLLECTION/URINALYSIS  
PANEL**Nov 25, 1996  
20 days to decisionK964422 · Product code: **DIF** · Toxicology  
Source: <https://www.510kdatabase.net/k964422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Nov 5, 1996
Decision date	Nov 25, 1996
Days to decision	20 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	RITA SMITH
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/k964422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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