

**K990377 ONTRAK TESTCUP M2K AND ONTRAK TESTSTIK  
POSITIVE CONTROL, MODEL 11 18544, ONTRAK TESTCUP  
M2K AND ONTRAK TESTSTICK NEGATIV**Feb 26, 1999  
18 days to decisionK990377 · Product code: **DIF** · Toxicology  
Source: <https://www.510kdatabase.net/k990377/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Feb 8, 1999
Decision date	Feb 26, 1999
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBBETT
510(k) history	264 submissions · 263 cleared · 1999-2013

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