

K994030 ONTRAK TESTCUP 5, CAT. 07 6481 7Jan 27, 2000
62 days to decisionK994030 · Product code: **LCM** · Toxicology
Source: <https://www.510kdatabase.net/k994030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Nov 26, 1999
Decision date	Jan 27, 2000
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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