

K001356 ONTRAK TESTCUP PRO-5, MODEL 1986678Jul 10, 2000
73 days to decisionK001356 · Product code: **DJC** · Toxicology
Source: <https://www.510kdatabase.net/k001356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	Apr 28, 2000
Decision date	Jul 10, 2000
Days to decision	73 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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