

K070200 TDM CONTROL SET, MODEL CAT# 04521536Mar 19, 2007
56 days to decisionK070200 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k070200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jan 22, 2007
Decision date	Mar 19, 2007
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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