

**K962165 COBAS-FP TDM CALIBRATION VERIFICATION TEST SET**Jun 26, 1996  
22 days to decisionK962165 · Product code: **DIF** · Toxicology  
Source: <https://www.510kdatabase.net/k962165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jun 4, 1996
Decision date	Jun 26, 1996
Days to decision	22 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/k962165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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