

**K843913 COBAS FP TDM CONTROLS**Oct 30, 1984  
26 days to decisionK843913 · Product code: **DIF** · Toxicology  
Source: <https://www.510kdatabase.net/k843913/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Oct 4, 1984
Decision date	Oct 30, 1984
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	GRIFFIN FITZGERAL
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/k843913/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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