

K000784 THE CARDIAC READER SYSTEMMay 18, 2000
69 days to decisionK000784 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k000784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Mar 10, 2000
Decision date	May 18, 2000
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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