

K014024 MODIFICATION TO ALPHA DX SYSTEMDec 18, 2001
12 days to decisionK014024 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k014024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Dec 6, 2001
Decision date	Dec 18, 2001
Days to decision	12 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	First Medical, Inc.
Location	Irvine, CA, US
Contact	GREG HOLLAND
510(k) history	4 submissions · 4 cleared · 1998-2001

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