

K013118 MODIFICATION TO ALPHA DX SYSTEMOct 15, 2001
27 days to decisionK013118 · Product code: **JHX** · Chemistry
Source: <https://www.510kdatabase.net/k013118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Sep 18, 2001
Decision date	Oct 15, 2001
Days to decision	27 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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