

K042924 ARCHITECT STAT MYO IMMUNOASSAYJan 24, 2005
94 days to decisionK042924 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k042924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Oct 22, 2004
Decision date	Jan 24, 2005
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher Diagnostics
Location	Mchenry, IL, US
Contact	JOSEFINA INFANTAS
510(k) history	16 submissions · 16 cleared · 1983-2017

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