

K042732 ARCHITECT CA 15-3 ASSAYDec 22, 2004
82 days to decisionK042732 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k042732/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Oct 1, 2004
Decision date	Dec 22, 2004
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics, Inc.
Location	North Caldwell, NJ, US
Contact	KIMBERLY PETERSON
510(k) history	45 submissions · 43 cleared · 1989-2025

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