

K100831 CYFRA 21-1 EIA MODEL 211-10May 26, 2011
428 days to decisionK100831 · Product code: **OVK** · Immunology
Source: <https://www.510kdatabase.net/k100831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytokeratin Fragments 21-1 Eia Kit (OVK)
Date received	Mar 24, 2010
Decision date	May 26, 2011
Days to decision	428 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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