

K250925 ADVIA Centaur Cytokeratin Fragment 21-1Dec 16, 2025
264 days to decisionK250925 · Product code: **OVK** · Immunology
Source: <https://www.510kdatabase.net/k250925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytokeratin Fragments 21-1 Eia Kit (OVK)
Date received	Mar 27, 2025
Decision date	Dec 16, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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