

**K160915 Elecsys CYFRA 21-1, Elecsys CYFRA 21-1 CalSet,
PreciControl Tumor Marker**Dec 14, 2016
257 days to decisionK160915 · Product code: **OVK** · Immunology
Source: <https://www.510kdatabase.net/k160915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytokeratin Fragments 21-1 Eia Kit (OVK)
Date received	Apr 1, 2016
Decision date	Dec 14, 2016
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Adam Clark
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...

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