

**K181492 Elecsys CA 15-3 II**Jun 22, 2018  
16 days to decisionK181492 · Product code: **MOI** · Immunology  
Source: <https://www.510kdatabase.net/k181492/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Jun 6, 2018
Decision date	Jun 22, 2018
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	Adennis Cora
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
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...

---