

**K122242 ELECSYS CA 15-3 II CALCHECK 5**Dec 5, 2012  
131 days to decisionK122242 · Product code: **JJX** · Immunology  
Source: <https://www.510kdatabase.net/k122242/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received         | Jul 27, 2012  |
| Decision date         | Dec 5, 2012   |
| Days to decision      | 131 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics</b>  |
| Location       | Indianapolis, IN, US  |
| Contact        | EDIE EADS   |
| 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...

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