

**K102044 ELECSYS DIGOXIN CALCHECK 5**Aug 31, 2010  
41 days to decisionK102044 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k102044/>**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 21, 2010  |
| Decision date         | Aug 31, 2010  |
| Days to decision      | 41 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics</b>  |
| Location       | Indianapolis, IN, US  |
| Contact        | KELLY COLLEEN O'NEILL;MAINE ADAMS   |
| 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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