

**K180693 CoaguChek XS Pro System**Apr 19, 2018  
34 days to decisionK180693 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k180693/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Test, Time, Prothrombin (GJS)      |
| Date received         | Mar 16, 2018                       |
| Decision date         | Apr 19, 2018                       |
| Days to decision      | 34 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics</b>  |
| Location       | Indianapolis, IN, US  |
| Contact        | Angie Clements  |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k180693/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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