

K170960 CoaguChek Vantus SystemDec 25, 2017
269 days to decisionK170960 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k170960/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Time, Prothrombin (GJS) |
| Date received | Mar 31, 2017 |
| Decision date | Dec 25, 2017 |
| Days to decision | 269 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics |
| Location | Indianapolis, IN, US |
| Contact | Justin Davis |
| 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...