



October 24, 2025

Roche Diagnostics
Todd Matczak
Regulatory Affairs Manager
9115 Hague Rd
Indianapolis, Indiana 46250

Re: K253188
Trade/Device Name: CoaguChek XS Plus System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: September 26, 2025
Received: September 26, 2025

Dear Todd Matczak:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell

Takeesha Taylor-Bell
Deputy Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253188

Device Name
CoaguChek® XS Plus System

Indications for Use (Describe)

The CoaguChek XS Plus System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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CoaguChek® XS Plus System

Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Special 510(k) Premarket Notification.

The **CoaguChek® XS Plus System** is a prothrombin time test system, a Class II medical device according to 21 CFR 864.7750.

The purpose of this Special 510(k) Premarket Notification is to obtain FDA review and clearance for the **CoaguChek® XS Plus System** for the following changes since its previous clearance, K180684:

- **Meter housing:** The meter housing material has remained the same as cleared under K180684, but now includes a clear plastic window on the side of the meter to allow for the utilization of a new barcode scanner. The meter housing was also modified internally to accept a rechargeable battery pack with a new dimensional footprint.
- **Cleaning and Disinfection:** A new routine maintenance cleaning process with water has been introduced to reduce potential disinfectant build up on the test strip guide. In addition, cleaning of the clear plastic barcode window with a dry cloth has been introduced. All other Cleaning and Disinfection processes, procedures, and schedules remain the same as cleared under K180684.

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|-----------------------------------|--|
| Submitter Name | Roche Diagnostics |
| Address | Roche Diagnostics 9115 Hague Rd Indianapolis IN 46250 (317) 521-3723 |
| Contact | Todd M. Matczak Phone: (317) 749-6148 Email: todd.matczak@roche.com |
| Date Prepared | October 24 th , 2025 |
| Proprietary Name | CoaguChek® XS Plus System |
| Common Name | Prothrombin time test |
| Classification Name | 864.7750 - Prothrombin time test |
| Product Codes | GJS (Class 2) - Test, Time, Prothrombin, 21 CFR 864.7750 |
| Predicate Devices | CoaguChek® XS Plus System , cleared in K180684, on April 19 th , 2018. |
| Establishment Registration | For the CoaguChek® XS Plus System , the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. |

1. DEVICE DESCRIPTION

The modifications in scope of this Special 510(k) do not impact the device description.

The **CoaguChek® XS Plus system** is a portable coagulation monitoring system to monitor prothrombin time (PT) in patients receiving oral anticoagulant therapy. The system uses the amperometric detection of thrombin in the blood sample. A test strip is used to determine a PT value from 8 µL of whole blood. Onboard quality control is available on every test strip and the system also features an optional external quality control material (**CoaguChek XS PT Control**).

2. INDICATIONS FOR USE

The modifications in scope of this Special 510(k) do not impact the intended use or indications for use of the system. Therefore, the Intended Use and Indications for Use for the **CoaguChek® XS Plus System** remains the same as the cleared **CoaguChek® XS Plus System** (K180684).

“The CoaguChek XS Plus system is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.”

3. TECHNOLOGICAL CHARACTERISTICS

The fundamental scientific technology of the **CoaguChek® XS Plus System** has not changed since its prior clearance K180684. The following remains unchanged:

- Measurement principle, technology, circuit, and algorithm for calculating measurement results.
- Sample type, sample volume, and measuring range.
- Performance specifications and performance claims in device labeling.

4. INSTRUMENT CLEANING AND DISINFECTION STUDIES

Robustness and effectiveness cleaning and disinfecting testing on the **CoaguChek® XS Plus System** for the new material of the barcode reader window, and the new routine maintenance cleaning of the test strip guide, demonstrated that the device meets the performance requirements for its intended use.

Acceptance criteria were met when testing with venous blood on the **CoaguChek® XS Plus** meters that had been subjected to 10,950 cleaning and disinfection cycles, and 156 test strip guide maintenance cleaning cycles, representing three-years lifetime of the meter based on a testing frequency of 10 tests per day.

Neither meter accuracy nor meter functionality were impacted by the cleaning and disinfection process or procedure.

5. CONCLUSION

The submitted information in this premarket notification supports a substantial equivalence decision for the **CoaguChek® XS Plus System**.