December 25, 2017

Roche Diagnostics
Justin Davis
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, Indiana 46250

Re: K170960
Trade/Device Name: CoaguChek Vantus System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: November 24, 2017
Received: November 27, 2017

Dear Justin Davis:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170960

Device Name
CoaguChek Vantus System

Indications for Use *(Describe)*
The CoaguChek® Vantus System measures an INR (International Normalized Ratio) based on a prothrombin time (PT) response to monitor the effect of a therapy with vitamin K antagonists by using the CoaguChek XS PT test strips. The CoaguChek Vantus System uses fresh capillary whole blood from a finger stick.

The system is intended for properly selected and suitable trained users on the prescription of the treating doctor.

Users should be stabilized on anticoagulation with vitamin K antagonists for at least 6 weeks prior to single patient self-testing with the CoaguChek Vantus System.

The CoaguChek Vantus System is intended for single patient self-testing only for adults, age 22 years and older.

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.

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CoaguChek Vantus System 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 Premarket Notification 510(k).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the CoaguChek Vantus System.

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Justin Davis Phone: (317) 521-6024 FAX: (317) 521-2324 Email: justin.davis@roche.com
Date Prepared	March 30, 2017
Proprietary Name	CoaguChek Vantus System
Common Name	CoaguChek Vantus System
Classification Name	Test Time Prothrombin Prothrombin Time Test
Product Codes, Regulation Numbers	GJS, 21 CFR 864.7750
Predicate Devices	CoaguChek XS System, K062925
Establishment Registration	For the CoaguChek Vantus System, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics in the United States is 1823260.

1. DEVICE DESCRIPTION

1.1. CoaguChek Vantus System

The CoaguChek Vantus consists of a handheld meter and associated test strips.

The CoaguChek Vantus meter is a small handheld instrument intended for the quantitative measurement of INR (International Normalized Ratio) based on a prothrombin time (PT) response, by using a single electrochemical test strip. It is designed for ease of use and is intended for patient self-testing only.

1.2. CoaguChek XS PT Test Strip

The CoaguChek XS PT Test strip contains a lyophilized reagent (reagent in dried form). The reactive components of this reagent consist of thromboplastin and a peptide substrate. When a sample is applied, thromboplastin activates coagulation, which leads to the formation of thrombin. At the same time, the meter starts to measure the time. The enzyme thrombin cleaves the peptide substrate, generating an electrochemical signal. Depending on the time elapsed when it first appears, this signal is then converted by means of an algorithm into customary coagulation units and the result is displayed.

2. INTENDED USE

The CoaguChek® Vantus System measures an INR (International Normalized Ratio) based on a prothrombin time (PT) response to monitor the effect of a therapy with vitamin K antagonists by using the CoaguChek XS PT test strips. The CoaguChek Vantus System uses fresh capillary whole blood from a finger stick.

The system is intended for properly selected and suitable trained users on the prescription of the treating doctor.

Users should be stabilized on anticoagulation with vitamin K antagonists for at least 6 weeks prior to single patient self-testing with the CoaguChek Vantus System.

The CoaguChek Vantus System is intended for single patient self-testing only for adults, age 22 years and older.

3. TECHNOLOGICAL CHARACTERISTICS

The following tables compare the CoaguChek Vantus System with its predicate device, CoaguChek XS System (K062925).

Candidate Device Name	Predicate Device Name	K-Number
CoaguChek Vantus System	CoaguChek XS System	K062925

Table 1: Instrument and Assay Comparison

Feature	CoaguChek XS System (K062925)	CoaguChek Vantus System
Intended Use	The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self- testing with the CoaguChek XS System.	The CoaguChek® Vantus System measures an INR (International Normalized Ratio) based on a prothrombin time (PT) response to monitor the effect of a therapy with vitamin K antagonists by using the CoaguChek XS PT test strips. The CoaguChek Vantus System uses fresh capillary whole blood from a finger stick. The system is intended for properly selected and suitable trained users on the prescription of the treating doctor. Users should be stabilized on anticoagulation with vitamin K antagonists for at least 6 weeks prior to single patient self-testing with the CoaguChek Vantus System. The CoaguChek Vantus System is intended for single patient self-testing only for adults, age 22 years and older.
Indications for Use	Same as Intended Use	Same as Intended Use
Test Strip	CoaguChek XS PT Test Strip	Same
Sample Type	Capillary Whole Blood	Same
Operating Principle	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same
Reagent Test Strip Principle	Human recombinant thromboplastin	Same
Sample Volume	The blood drop must be a minimum of 8 µl	Same
Measuring Range	0.8 to 8.0 INR	0.8 to 6.0 INR
On-Board Control	Built into each CoaguChek XS PT Test Strip	Same
Hematocrit Range	Hematocrit ranges between 25-55% have no significant effect on test results	Same
Bilirubin	Bilirubin up to 30 mg/dL have no significant effect on test results	Same

Feature	CoaguChek XS System (K062925)	CoaguChek Vantus System
Triglyceride	Lipemic samples containing up to 500 mg/dL of triglycerides have no significant effect on test results	Same
Hemolysis	Hemolysis up to 1000 mg/dL have no significant effect on test results	Same
Heparin	Test results are unaffected by heparin concentrations up to 0.8 U/mL	Same
Low Molecular Weight Heparin	The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL	Same
Memory Capacity	300 test results with date and time No test strip lot information stored (code chip data)	300 test results with date and time Code chip data from up to 5 test strip lots can be stored
Communication Interface	Infrared	Bluetooth, USB

4. NON-CLINICAL PERFORMANCE EVALUATION

The following internal performance data were provided in support of the substantial equivalence determination:

- Endogenous Interferences - Hematocrit/Bilirubin/Triglycerides/Hemolysis/Heparin
- Exogenous Interferences - Drugs
- Stability

4.1. Linearity/Assay Reportable Range

4.1.1. Linearity

A linearity study is not applicable for the CoaguChek Vantus System.

4.1.2. Assay Reportable Range

The assay reportable range (0.8 - 6.0 INR) of the CoaguChek Vantus System was established through method comparison studies against both the predicate (Roche CoaguChek XS System) and the reference device (Sysmex CA-1500 laboratory analyzer). Dade Innovin Reagent was used for prothrombin time (PT) determinations.

4.2. Test Strip Stability

4.2.1. Traceability

Each lot of CoaguChek XS PT Test Strips is factory calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation.

4.2.1.1. Closed Vial and Transport Stability

The CoaguChek XS PT Test strips were stored at +2-8 °C and +26-30°C and tested after a storage time of 3, 6, 16, and 25 months. The 25 month time point captures the component of transport stability, as the 25 months includes a 5-day period of stressed storage at +45 °C (±2 °C).

4.2.1.2. Open Vial Stability

Open vial stability simulates the repeated opening and closing of the vial by the customer when strips are removed from the vial for measurement. Open vial stability was tested by opening the vials once per day for at least 1 minute at +32 °C, 85 % relative humidity (RH) over a period of 30 days.

4.2.1.3. Out of Vial Stability

Out of vial stability was tested to prove that the test strips can be kept outside the vial before measurement for at least 10 minutes when directly exposed to +32 °C, 85 % RH. This was verified by storing the test strip outside the vial under the specified environmental conditions for 14 minutes before measurement

4.3. Detection Limit/Factor Sensitivity

For Factor Sensitivity studies, four CoaguChek XS PT Test strip lots were used.

Standard human plasma was mixed with varying amounts of factor II, V, VII or X deficient plasma to obtain plasma samples with different factor activities (0, 1, 10, 20, 30, 40, 50, 60, 70, 80, 90, and 100 %). For each test strip lot, at least 4 measurements were performed per coagulation factor and dilution level.

Factor sensitivities were calculated according to CLSI guidelines (CLSI H47-A2; Vol.28, Appendix D). The study verifies Factor Sensitivity at the following levels: Factor II <31%; Factor V <46%; Factor VII <44%; and Factor X <50%.

4.4. Analytical Specificity

4.4.1. Endogenous and Exogenous Interferences

The interference studies were performed for the following interferents: bilirubin, hemolysis, heparin, low molecular weight heparin, triglycerides. In addition, an interference study was conducted to characterize the levels of other known drugs: clopidogrel , fondaparinux, rivaroxaban, apixaban, dabigatran, edoxaban.

Interference limits were established using up to four CoaguChek XS PT Test strip lots, using fresh citrated venous whole blood from both normal and warfarin blood samples spiked separately with the interferents.

Interferent	Concentration
Bilirubin	Up to 30 mg/dL
Hemolysis	Up to 1000 mg/dL
Heparin	Up to 0.8 U/mL
Low Molecular Weight Heparin	Up to 2 IU anti-factor XA activity/mL
Triglycerides	Up to 500 mg/dL
Clopidogrel	Up to 20 mg/dL
Fondaparinux	Up to 0.5 mg/L
Rivaroxaban	Cannot be tested with system
Apixaban	Cannot be tested with system
Dabigatran	Cannot be tested with system
Edoxaban	Cannot be tested with system

4.5. Assay Cut-Off

Not applicable.

5. EXTERNAL (CLINICAL) TESTING

5.1. Precision

5.1.1. Repeatability

A total of 688 specimens from subjects on oral anticoagulation therapy with vitamin K antagonists and coagulation healthy subjects were collected. In total 344 repeatability series were performed at four PoC sites. Data analysis was carried out by PoC site, by test strip lot and by clinically relevant ranges (<2.0, 2.0-3.5, >3.5-4.5, >4.5 INR).

Table 2: Summary of Repeatability for CoaguChek Vantus

Blood	**< 2.0 INR**	**2.0-3.5 INR**	**> 3.5 – 4.5 INR**	**> 4.5 – 6.0 INR**
N	200	394	70	24
Mean (INR)	1.1	2.6	4.0	4.9
SD (INR)	0.04	0.08	0.12	0.07
CV (%)	3.8	3.1	3.2	1.5

5.1.2. Reproducibility

The intermediate precision experiment according to the CLSI Guideline EP05-A3 was conducted at all 4 PoC sites, with three lots of CoaguChek XS PT Test strips. The data was obtained from HCP measurements of three lots of CoaguChek XS PT controls covering four levels of controls.

Table 3: Summary of Reproducibility for CoaguChek Vantus

			Repeatability (Within Run)		**Between Run**		**Between Strip Lot**		**Between Day**		**Between Site**		**Reproducibility**	
Control Level	**N**	**Mean**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
1	1040	1.32	0.03	2.4	0.01	0.6	0.04	2.9	0.01	0.7	0.01	1.0	0.05	4.0
2	1040	2.79	0.11	4.0	0.00	0.0	0.02	0.7	0.00	0.0	0.03	1.0	0.12	4.2
3	708	5.85	0.17	2.9	0.07	1.2	0.14	2.3	0.04	0.8	0.02	0.4	0.24	4.0
4	712	3.39	0.09	2.7	0.04	1.2	0.03	1.0	0.00	0.0	0.03	0.9	0.11	3.2

5.2. Method Comparison

5.2.1. Method Comparison versus Predicate

Accuracy was evaluated by comparing the CoaguChek Vantus System against the predicate device, the CoaguChek XS System. The clinical method comparison study was performed using capillary whole blood samples from subjects not receiving warfarin or any other anticoagulant and from subjects currently on warfarin therapy. The method comparison study was conducted across 4 PoC sites using three 3 CoaguChek XS PT Test strip lots.

Table 4: CoaguChek Vantus System vs CoaguChek XS System

Site	N	Slope (95% CI)	Intercept (95% CI)	Pearson r
All	207	1.00 (1.00, 1.03)	0.1 (0.1, 0.1)	0.99

5.2.2. Method Comparison versus Reference System

Accuracy was also evaluated by comparing the INR results of capillary samples measured on the CoaguChek Vantus System against the INR of venous plasma samples measured on Sysmex CA 1500 laboratory analyzer using Dade Innovin recombinant human tissue thromboplastin reagent (reference device). The method comparison study was performed s across four (4) sites using CoaguChek XS PT Test strip lots. Results of INR values measured on CoaguChek Vantus System fingerstick capillary whole blood samples were compared to the INR measured on Innovin using venous plasma samples. The data from individual sites were combined and a Passing-Bablok regression analysis was performed.

Table 5: CoaguChek Vantus System vs Innovin

Site	N	Slope (95% CI)	Intercept (95% CI)	Pearson r
1	67	0.94 (0.85,1.02)	0.2 (-0.0,0.4)	0.86
2	43	1.02 (0.92,1.15)	0.1 (-0.2,0.3)	0.97
3	47	1.03 (0.94,1.12)	0.0 (-0.2,0.2)	0.97

Site	N	Slope (95% CI)	Intercept (95% CI)	Pearson r
4	43	0.95 (0.82,1.13)	0.2 (-0.3,0.5)	0.93
All	200	0.98 (0.93, 1.03)	0.1 (0.0, 0.3)	0.91

5.3. Sample Matrix Comparison

Not applicable, as the CoaguChek Vantus System is intended for use with capillary whole blood samples only.

5.4. Expected Values / Reference Range

A normal range study was conducted on 121 healthy subjects not on anticoagulation therapy. Capillary whole blood sample testing performed on the subjects not using vitamin K antagonist drugs demonstrated that 95% of the INRs ranged between 0.9 - 1.1.

6. SYSTEM DESCRIPTIONS

6.1. Modes of Operation

The CoaguChek Vantus System is a closed system, which only uses the CoaguChek XS PT Test Strip; other test strips will not work with the instrument.

6.2. Software

The user interface of the CoaguChek Vantus instrument guides the user through the test procedure step by step. The user only needs to insert the code chip, turn the meter on, insert the test strip, and apply a blood sample. The CoaguChek Vantus meter measures the coagulation time and displays the result. After the test is completed, the meter automatically saves the test result.

The system also includes Bluetooth connectivity to allow transfer of INR results.

6.3. Specimen Sampling and Handling

The CoaguChek XS PT Test strip is intended for single-use only. Once the test strip is inserted into the analyzer, a drop of fresh capillary whole blood sample collected by fingerstick is manually applied to the test strip target area and analyzed by the CoaguChek Vantus instrument.

6.4. Calibration

Each lot of CoaguChek XS PT Test strips is factory calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation. This lot-specific calibration information is embedded within the code chip, which is required by the CoaguChek Vantus instrument prior to using the specific lot of the CoaguChek XS PT Test strip.

6.5. Quality Control

The CoaguChek Vantus System provides On-Board Controls (OBC), which provide a quality control check for each individual CoaguChek XS PT Test strip used with the CoaguChek Vantus instrument. There are no additional steps required by the user to activate the OBC.

When a test strip is inserted, the CoaguChek Vantus instrument, the first check assesses potential issues with the reagent. The second check ensures that the test strip has not been exposed to environmental conditions or physical stresses, like bending. If either of these checks does not pass, then no PT/INR result is provided.

7. CONCLUSIONS

The submitted information in this premarket notification supports a substantial equivalence decision.

The results of these studies demonstrate that the CoaguChek Vantus System is similar to the predicate. The data presented are a summary of external clinical evaluation, internal laboratory evaluation, and software development information.