510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k092940

B. Purpose for Submission:
Clearance of a device for patient self-testing

C. Measurand:
Prothrombin Time

D. Type of Test:
Electrochemical

E. Applicant:
Roche Diagnostics Corporation

F. Proprietary and Established Names:
CoaguChek® XS Plus System for Patient Self-Testing

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.7750 - Prothrombin Time Test
2. Classification:
   Class II
3. Product code:
   GJS - Prothrombin Time Test
4. Panel:
   81 Hematology

H. Intended Use:

1. Intended use(s):
   The CoaguChek® XS Plus System for Patient Self-Testing measures blood-clotting time for people who are taking warfarin anticoagulation medications. The CoaguChek XS Plus System for Patient Self-Testing 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.
2. Indication(s) for use:
   Same as Intended Use
3. Special conditions for use statement(s):
   Prescription Home Use
4. Special instrument requirements:
   CoaguChek® XS Plus

I. Device Description:

The CoaguChek® XS Plus for Patient Self-Testing 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 10µL of whole blood. The system features onboard quality control on every test strip as well as optional external quality control material. The test strip incorporates quality control material that assesses strip integrity. The system also features a QC lockout feature which prevents the operator from performing a test if the QC results fail.

The CoaguChek® XS Plus for Patient Self-Testing automatically stores up to 500 test results with date, time, patient ID, and operator ID, along with 60 code chip records in memory.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Diagnostics CoaguChek XS Plus System
2. Predicate 510(k) number(s):
   k071041
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The CoaguChek® XS Plus System for Patient Self-Testing measures blood-clotting time for people who are taking warfarin anticoagulation medications. The CoaguChek XS Plus System for Patient Self-Testing uses blood form 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.	Same
Measuring Range	0.8 - 8.0 INR	Same
Sample Volume	10 µL	Same
Reagent	Human recombinant thromboplastin	Same

Differences		
Item	Device	Predicate
Setting	For patient self-testers	For Professional Use
Software	No bar code reader	Bar code reader
Hardware	No handheld base unit	Handheld base unit

K. Standard/Guidance Document referenced (if applicable):

None

L. Test Principle:

When a blood sample is applied to the test strip, thromboplastin activates the coagulation cascade which leads to the formation of thrombin. Thrombin cleaves the thrombin substrate creating an electrochemically active peptide, which generates an electrical signal. The signal is converted to an INR value and displayed by the CoaguChek XS System.

The on-board quality control is a bi-level control that assesses test strip integrity. The prothrombin time (PT) test and quality control (QC) testing are performed simultaneously. The test system determines whether the quality control is within preset limits. If it is, the meter displays a short term "QC✓", and then the PT test result. If the QC is not within limits, the meter displays "error QC", and no PT test result will be displayed.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      At each study site, enrolled patients and the healthcare professionals performed duplicate measurements. The precision of duplicates was calculated for both the subjects and healthcare professionals, and the data presented by site as well as overall. The acceptance criterion was set as ≤ 10% INR mean bias between the patients and healthcare professional. Mean bias was calculated using the first patient and the first healthcare professional result. All visits met the acceptance criteria.

	User Results	Professional Results
N	296	308
Mean	2.47	2.45
SD	0.135	0.101
CV	5.47	4.12

   b. *Linearity/assay reportable range:*
      Referred to k071041
   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      Referred to k071041
   d. *Detection limit:*
      Not applicable
   e. *Analytical specificity:*
      Not applicable
   f. *Assay cut-off:*
      Not applicable
2. Comparison studies:
   a. *Method comparison with predicate device:*
      The method comparison data was submitted, reviewed, and cleared under k071041.
      When compared to the lab reference:
      Venous - N=811, y = 1.090X – 0.2, r = 0.974
      Capillary – N = 822, y = 1.075X – 0.1, r = 0.972
   b. *Matrix comparison:*
      Not applicable
3. Clinical studies:
   A three site user study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals. Both groups used the CoaguChek XS Plus System. Following face-to-face training, 103 subjects were sent home to self-test, for up to 8 weeks. Three study site visits were scheduled to collect user vs technician data. Regression analysis was performed for visits 2, 3, 4, and overall. Results demonstrated acceptable correlation.

Visit number	N	Slope	Intercept	Correlation
2	101	1.00	0.00	0.976
3	103	1.00	0.00	0.946
4	103	1.00	0.00	0.972
Overall	307	1.00	0.00	0.963

The mean bias between the patient and health care professional were calculated for the sites visits (Visits 2, 3, 4 and overall). Acceptance criteria for mean bias was set as <10% INR. All visits met the acceptance criteria.

	Visit 2	Visit 3	Visit 4	Overall
Mean Bias	**1.0%**	**2.6%**	**1.3%**	**1.6%**

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Normal range testing was conducted on 121 patients who were not on oral anticoagulant therapy. Both capillary and venous samples were collect from each patient. Samples were tested on two lots of CoaguChek XS PT strips. Results demonstrated a normal range of 0.9 to 1.1 INR with more than 95% of all results falling within that range.

N. Instrument Name:
CoaguChek XS Plus

O. System Descriptions:

1. Modes of Operation:
Manual, closed system

2. Software:
The CoaguChek XS software controls the user interface, buttons used to navigate the user interface and to configure the device, storage of patient results, transfer of measurement results using serial infrared communication in an open mode, transfer of production and calibration results using serial infrared communication in a protected mode, reading and storage of specific information for strip LOT from code key, calculation of PT time based on data received from measurement cycle, and checks for failsafe in order to recognize malfunctions of the measurement electronics or malfunctions within the strip used for testing.
The applicant's Hazard Analysis and software development processes for this device were reviewed under K060978.
Yes ___✓__ or No _____

3. Specimen Identification:
Date and time of testing along with patient identifier information is recorded by the CoaguChek XS meter.

4. Specimen Sampling and Handling:
Whole blood is manually applied to the target area of the test strip either from the top or side of the strip.

5. Calibration:
The CoaguChek XS Test strips are calibrated to a master reagent lot which has in turn

been calibrated to a WHO International Reference Preparations (rTF/95) using the manual tilt tube method.

6. Quality Control:
   The CoaguChek XS System incorporates a bi-level on-board quality control (OBC) within the CoaguChek XS test strip that monitors test strip integrity. Level 1 OBC detects strip defects such as reagent defects, capillary compression and electrode defects. Level 2 OBC directly measures strip damage due to such things as exposure to increased humidity, light, and temperature.
   The pre-determined OBC ranges are programmed into the lot specific code chip that is packaged with the matching test strip lot.
   Acceptable data was presented validating the OBC.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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