510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K062925

B. Purpose for Submission:

Clearance of a new instrument and test strip

C. Measurand:

Prothrombin Time

D. Type of Test:

Electrochemical

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

CoaguChek® XS System (Patient Self-testing)

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.7750

2. Classification:

   Class II

3. Product code:

   GJS

4. Panel:

   81 Hematology

H. Intended Use:

1. Intended use(s):

   The CoaguChek XS 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 system uses capillary blood.

2. Indication(s) for use:

3. Special conditions for use statement(s):

   Intended for home use

4. Special instrument requirements:

I. Device Description:

The CoaguChek® XS System includes a meter and CoaguChek® XS PT test strips. The test strip contains a human recombinant tissue factor, and is calibrated to an ISI of 1.0.

The test strip incorporates quality control material that accesses strip integrity.

The CoaguChek® XS meter automatically stores up to 100 test results along with their dates and times in memory.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Roche Diagnostics CoaguChek XS System

2. Predicate 510(k) number(s):

   K060978

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Measure prothrombin time	same
Technology	Electrochemical with amperometric detection of thrombin activity	same
Dosing	Top and side dosing	same

Differences		
Item	Device	Predicate
Indications	Home users	Professional use

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

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 accesses test strip integrity. The PT test and 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:

Precision of duplicates for capillary blood results was calculated for both trained users and healthcare professional. The following results were obtained:

	User results	Professional Results
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

b. Linearity/assay reportable range:

Established under K060978

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Established under K060978

d. Detection limit:

e. Analytical specificity:

Established under K060978

f. Assay cut-off:

2. Comparison studies:

a. Method comparison with predicate device:

Study compared test results obtained by trained users to results obtained by healthcare professionals using the CoaguChek XS meter. The patient tested once a week at home for 8 weeks, with 3 scheduled visits to their study site. At the site visit the patient performed two tests on the CoaguChek XS meter, and the healthcare professional performed two tests on the subject using the subject's meter and supplies. A venous reference sample (3.2% sodium citrate) was collected on site visits 2 and 4 and the healthcare professional checked the setup of the meter. 107 patients were enrolled, and a total of 91 patients completed all four visits. Comparing test results obtained by patients with results obtained by the healthcare professional demonstration good correlation ($y = 1.00x-0$, $r= 0.977$, $n=463$). Test results obtained by the patient was also compared to a laboratory-based plasma method with good results ($y = 1.154x – 0.2$, $r = 0.934$, $n=297$).

b. Matrix comparison:

3. Clinical studies:

a. Clinical Sensitivity:

b. Clinical specificity:

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

4. Clinical cut-off:

5. Expected values/Reference range:

Established under K060978

N. Instrument Name:

CoaguChek XS meter

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.

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___✓____ or No _____

3. Specimen Identification:

   Date and time of testing 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:

An instrument failsafe checklist was presented outlining the QC check made by the CoaguChek XS meter.

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.