510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k072920

B. Purpose for Submission:

Abbreviated submission for the clearance of a modification to the currently cleared CoaguChek XS Plus

C. Manufacturer and Instrument Name:

ROCHE DIAGNOSTICS CORP.

CoaguChek XS Plus Handheld Base Unit (HBU)

D. Type of Test or Tests Performed:

Prothrombin Time

E. System Descriptions:

1. Device Description:

   The Handheld Base Unit is an accessory to the CoaguChek XS Plus PT instrument that provides the ability to recharge the internal battery of the CoaguChek XS Plus and facilitates the connectivity of the CoaguChek XS Plus to an external computer in order to download the device memory.

2. Principles of Operation:

   The HBU uses a POCT1-A protocol to identify a docked instrument in order to trigger the automatic host communication. Connectivity between the HBU and CoaguChek XS Plus is established either via infrared or IrDA.

3. Modes of Operation:

   A switch (USB configuration switch), on the back side of the Handheld Base Unit, sets the BASE to one of three different modes of operation:

Position	Mode	Description
1	Ethernet	The BASE converts meter communication (IrDA) received on the BASE's IR window to wired Ethernet.
2	Serial & Ethernet	The BASE converts host communication (USB Comm) to serial infrared on the BASE's IR window. -or- The BASE converts meter communication (IrDA) received on the BASE's IR window to wired Ethernet. Note: The BASE cannot handle Serial & Ethernet conversion simultaneously. Both communication paths will be handled on after the other by means of timeouts.
3	Configuration	The BASE acts as a mass storage device on the USB port. Writing and reading files, using the mounted mass storage file system is the way to communicate with the BASE.

4. Specimen Identification:

   N/A

5. Specimen Sampling and Handling:

   N/A

6. Calibration:

   N/A

7. Quality Control:

   N/A

8. Software:

   FDA has reviewed applicants Hazard Analysis and Software Development

processes for this line of product types:

Yes___X____ or No_____

F. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
GJS	II	21 CFR 864.7750	81 Hematology

G. Intended Use:

1. Indication(s) for Use:

The device 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.

2. Special Conditions for Use Statement(s):

Prescription

H. Substantial Equivalence Information:

Similarities		
Item	Device	Predicate
Intended Use	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.	Same
Measuring	0.8- 8.0 INR	Same

range		
Reagent	Human recombinant thromboplastin	Same

Differences		
Item	Device	Predicate
Router Component:	HBU incorporates the router component into the HBU. Roche now has direct design control of this component.	Connected to a hospital network via an off-the-shelf router component.
Physical Characteristics	Serves as a docking station for the predicate device.	Uses docking station for charging and data transfer.

I. Special Control/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Medical device software - Software life cycle processes (62304 Ed. 1.0)

Other Standards

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff	**ODE**		**http://www.fda.gov/cdrh/ode/guidance/337.html**

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

   N/A

b. Precision/Reproducibility:

N/A

c. Linearity:

N/A

d. Carryover:

N/A

e. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

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

L. Conclusion:

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