K093460

MAR 18 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: March 15, 2010

2) Device name

Proprietary name: CoaguChek® XS Pro System
Common name: Prothrombin time test
Classification name: Prothrombin time test

3) Predicate device

The CoaguChek XS Pro System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, the CoaguChek XS Pro System is a modification of the previously cleared CoaguChek XS Plus System (K071041).

4) Device Description

The CoaguChek XS Pro System represents a modification of the CoaguChek XS Plus System to incorporate an embedded barcode scanner. The unmodified device was cleared for use under premarket notification K071041.

The intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s) described in this 510(k).

The fundamental scientific technology of this device has not changed as a result of the modification(s) described in this 510(k).

5) Intended Use The CoaguChek XS Pro System (CoaguChek XS Pro meter and CoguChek XS PT Test strips) quantitatively determines prothrombin time ("PT"), using capillary blood or whole blood from a vein (nonanticoagulated venous whole blood). It is indicated for use by healthcare professionals. The system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication (vitamin K antagonists, VKAs).

6) Similarities The table below indicates the similarities between the CoaguChek XS Plus System and the CoaguChek XS Pro System.

Topic	CoaguChek XS Plus System (predicate: unmodified device)	CoaguChek XS Pro System (modified device)
	General Features	
Intended use	Intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy.	The CoaguChek XS Pro System (CoaguChek XS Pro meter and CoguChek XS PT Test strips) quantitatively determines prothrombin time ("PT"), using capillary blood or whole blood from a vein (nonanticoagulated venous whole blood). It is indicated for use by healthcare professionals. The system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication (vitamin K antagonists, VKAs).
Fundamental technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same
Sample type	Fresh capillary or non-anticoagulated venous whole blood	Same
Test strip	The CoaguChek XS PT Test Strip	Same
Onboard control	Built into every strip and recognized by the meter	Same
External quality control	CoaguChek XS PT Controls are available as optional external controls	Same

Topic	CoaguChek XS Plus System (predicate: unmodified device)	CoaguChek XS Pro System (modified device)
System Performance Characteristics		
Measuring range	0.8 – 8.0 INR	Same
Hemotocrit 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
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

Topic	CoaguChek XS Plus System (predicate: unmodified device)	CoaguChek XS Pro System (modified device)
System Performance Characteristics		
Low Molecular Weight Heparin	The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2IU anti-factor Xa activity/mL	Same
Accuracy compared to the reference	**Venous Blood:** N=811 Slope= 1.090 Intercept = -0.2 Correlation = 0.974 **Capillary Blood:** N = 822 Slope = 1.075 Intercept = -0.1 Correlation = 0.972	Same
Whole Blood Precision	**Venous Blood:** N = 399 Mean INR = 2.32 SD = 0.046 CV = 2.00 **Capillary Blood:** N = 399 Mean INR = 2.26 SD = 0.077 CV = 3.39	Same
Control Precision	**Level 1:** N = 538 Mean INR = 1.18 SD = 0.04 CV = 3.37 **Level 2:** N = 535 Mean INR = 2.95 SD = 0.12 CV = 4.10	Same

Topic	CoaguChek XS Plus System (predicate: unmodified device)	CoaguChek XS Pro System (modified device)
	Hardware	
Measurement module (Measurement engine)	Converts raw signals from test strip into final PT result.	Same Measurement Module has **not** been modified
Handheld Basic Module	Provides the power management of the AC-adapter or rechargeable batteries and houses all the data management features.	Same Handheld Basic Module has **not** been modified
	Software	
Code chip function	Code chip information is stored in meter to identify test strip and liquid control information.	Same

7) Differences The table below indicates the modified features of the CoaguChek XS Pro System.

Topic	CoaguChek XS Plus System (predicate: unmodified device)	CoaguChek XS Pro System (modified device)
	General Features **Note: The test strip itself has not been modified**	
Capillary sample volume	Blood drop must be minimum **10 µl**	Blood drop must be minimum **8 µl**
	Code Chip Modifications	
Blood application time	**120 seconds**	**180 seconds**
Operating temperature	**18°** - 32 °C	**15°** - 32 °C
	Hardware	
Barcode Scanner	**External Barcode Scanner**	**Integrated Barcode Scanner**
Display	**LED Display**	**TFT Display**
Size	**185 x 98 x 42 mm**	**231 x 97 x 43 mm**
Weight	**311 g (without batteries)**	**350 g (without batteries)**
	Software	
Memory	**500** INR results, 500 QC results	**1000** INR results, 500 QC results
Display	**User interface shows images/icons**	**Upgraded display shows images/icons and more descriptive text.**

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

Roche Diagnostics
c/o Ms. Jennifer Tribbett
Regulatory Program Manager
9115 Hague Road
Indianapolis, Indiana 46250

MAR 18 2010

Re: k093460
Trade/Device Name: Coaguchek XS Pro System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Tribbett:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing

your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K093460

Device Name: **CoaguChek XS Pro System**

Indications For Use:

The CoaguChek XS Pro System (CoaguChek XS Pro meter and CoguChek XS PT Test strips) quantitatively determines prothrombin time ("PT"), using capillary blood or whole blood from a vein (nonanticoagulated venous whole blood). It is indicated for use by healthcare professionals. The system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication (vitamin K antagonists, VKAs).

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093460