K060978

AUG 1 1 2006

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: April 6, 2006

2) Device name

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

3) Predicate device

The Roche Diagnostics CoaguChek XS System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek S System (K020831).

4) Device Description

The CoaguChek XS is a 3rd generation CoaguChek meter which measures prothrombin time in fresh capillary or non-anticoagulated venous whole blood samples.

The CoaguChek XS System incorporates many of the perspectives shared by FDA during reviews of our previous systems, including but not limited to integrated quality control and a blood application area that is outside the meter.

The CoaguChek XS System includes a meter and CoaguChek XS PT test strips. Each box of test strips has its own code chip that you insert into the meter. The code chip contains important information about the test strips such as their expiration date and lot number. The meter and test strips work together to provide a safe and reliable system for testing blood-clotting time.

5) Intended Use The CoaguChek XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek XS System uses fresh capillary or non-anticoagulated venous whole blood.

6) Similarities to predicate device The CoaguChek XS System is similar to the predicate CoaguChek S System in the following items:

Topic	Comment
Intended Use	Both are intended to be used by professional healthcare providers for the quantitative prothrombin time (PT) testing to monitor warfarin therapy, using fresh capillary or non-anticoagulated venous whole blood.
Measuring Range	Both systems have a measuring range of 0.8 – 8.0 INR.
Closed System	Both systems use instrument and reagent strips that are provided by Roche and are intended to be used together.
Specimen collection and preparation instructions	These instructions are the same for both systems.
Sample Volume	Both require a minimum of 10 µL capillary blood
Thromboplastin	Both contain human recombinant thromboplastin, stabilizers and preservatives.
International Sensitivity Index	Both have an ISI established as 1.
Calibration of results	Both systems are traceable to the WHO reference method.

7) Differences from predicate device The following table lists the major differences between the CoaguChek XS System and the predicate CoaguChek S System.

Topic	CoaguChek XS System	CoaguChek S System (Predicate)
Technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity.	Dancing particle technology with optical detection of thrombin activity.
Quality Control	On-board fully integrated quality controls which use electrochemical signals to detect test strip integrity.	Liquid controls and external electronic quality control
Test Strip Dosing	Top and side dosing	Top dosing only
Start up	Instrument turns on with either the insertion of the test strip or the push of a button	Instrument turns on with the push of a button
Memory	100 test results with time & date	60 test results with time & date

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8) Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek XS System and the CoaguChek S System.

Claim	CoaguChek XS System	CoaguChek S System (Predicate)
Bilirubin	No significant effect up to 30 mg/dL	No significant effect up to 20 mg/dL
Hemolysis	No significant effect up to 1000 mg/dL	No significant effect up to 500 mg/dL
Triglycerides	No significant effect up to 500 mg/dL	No significant effect up to 500 mg/dL
Hematocrit	Hematocrit ranges between 25 – 55% do not significantly affect test results.	Hematocrit ranges between 32 – 52% do not significantly affect test results.
Heparin	Unaffected by heparin concentrations up to 0.8 U/mL.	Unaffected by heparin concentrations up to 2.0 U/mL.
Low Molecular Weight Heparin	Insensitive to low molecular weight heparins up to 2 IU anti-factor Xa activity/mL.	Insensitive to low molecular weight heparins up to 1 IU anti-factor Xa activity/mL.
Capillary Accuracy (All Sites)	Capillary blood on CoaguChek XS vs. venous plasma on a Sysmex Analyzer using Dade Innovin (ISI = 1.02) N= 700 y= 1.006x + 0.032 Correlation: 0.971	Capillary blood on CoaguChek S vs. venous plasma on MLA 900 using Ortho Recombiplastin (ISI = 1.03) N= 539 y= 1.150x – 0.25 Correlation: 0.965
Venous Accuracy (All Sites)	Venous Whole Blood: CoaguChek XS vs. Sysmex Analyzer using Dade Innovin (ISI = 1.02) N= 710 Y= 1.034x – 0.02 Correlation: 0.974	Venous Whole Blood: CoaguChek S vs. MLA 900 using Ortho Recombiplastin (ISI = 1.03) N= 761 Y= 1.150x – 0.24 Correlation: 0.970

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Performance characteristics *-Continued-*

Claim	CoaguChek XS System	CoaguChek S System (Predicate)
Precision with blood	Whole blood precision for venous and capillary samples was determined from sample duplicates collected at three external sites. Bland Altman plots for both capillary and venous blood are provided in the test strip insert. The following information represents the data that is graphically shown by the Bland Altman plots. Venous: N = 357 Mean = 2.59 INR SD = 0.06 CV = 2.42 Capillary: N = 344 Mean = 2.59 INR SD = 0.11 CV = 4.35	Whole blood precision was determined from sample duplicates at five external sites for the venous blood and four external sites for the capillary blood. Bland Altman plots for both capillary and venous blood are provided in the test strip insert. The following information represents the data that is graphically shown by the Bland Altman plots. Venous: N = 376 Mean = 2.5 INR SD = 0.11 CV = 4.43 Capillary: N = 268 Mean = 2.1 INR SD = 0.15 CV = 7.19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

ROCHE DIAGNOSTICS
c/o Jennifer Tribbett
9115 Hague Road
Indianapolis, IN 46256

AUG 1 1 2006

Re: k060978/S001
CoaguChek® XS System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: April 6, 2006
Received: April 10, 2006

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 either class II (Special Controls) or class III (PMA), 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD. PhD.
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060978

Device Name: CoaguChek® XS System

Indications For Use:

The CoaguChek XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek XS System uses fresh capillary or non-anticoagulated venous whole blood.

Prescription Use ___X____ 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 Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060978