K092940

MAR - 5 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: September 22, 2009

2) Device name

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

3) Predicate device

The Roche Diagnostics CoaguChek XS Plus System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS Plus System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS Plus System (professional) except the labeling has been modified and validated for patient self-testing.

The labeling created for the CoaguChek XS Plus System (patient self-testing) is substantially equivalent in format and content to the CoaguChek XS System (patient self-testing).

4) Device Description

The CoaguChek XS Plus System was previously cleared for professional use under premarket notification K071041.

This premarket notification is being submitted to obtain clearance for patient self-testing.

5) Intended Use

The CoaguChek XS Plus System measures blood-clotting time for people who are taking warfarin anticoagulation medications. The CoaguChek XS Plus System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor.

6) Comparison to Predicate Device

The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS Plus System (K071041):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated (on-board) Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

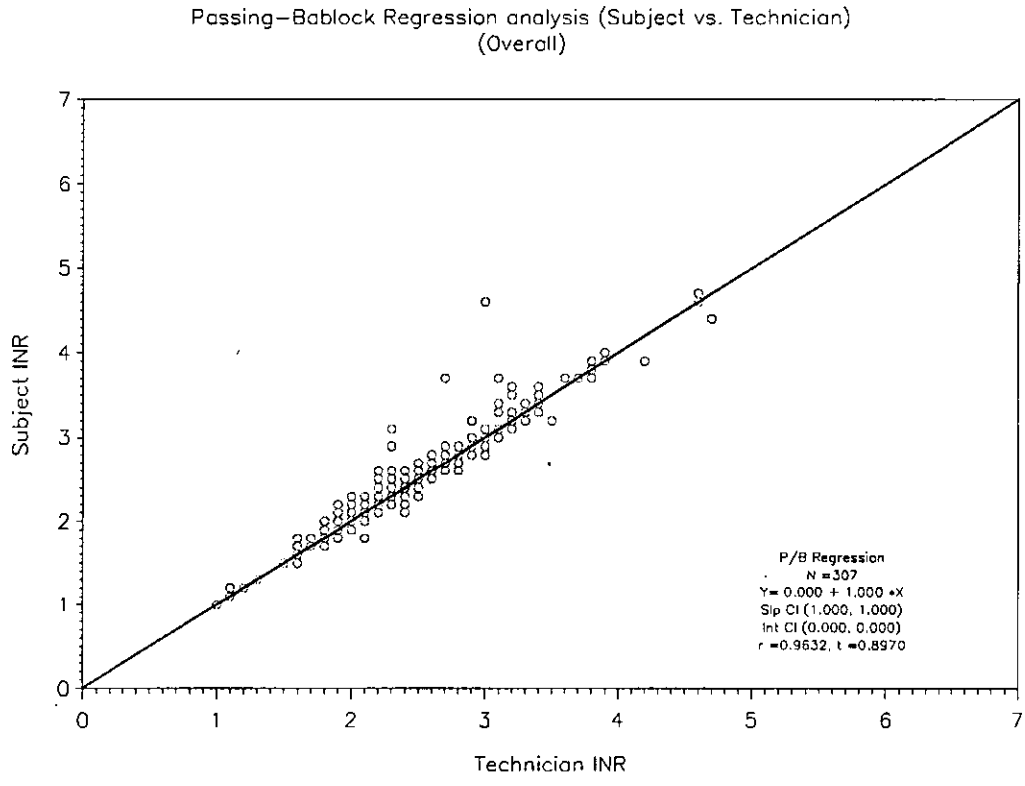
The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following face-to-face training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals. This study also demonstrated that self-tester results are consistent over time.

7) Performance characteristics

The performance characteristics that are impacted by the new user population were evaluated. The following information has been incorporated into our draft patient self-testing insert.

Claim	Statement
Accuracy	A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS Plus System. The correlation was very good, as indicated by the following statistics: N = 307, Slope = 1.000, Intercept = 0.0 and Correlation Coefficient = 0.963. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS Plus System.



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Study User Demographics	A clinical study was conducted by Roche Diagnostics, consisting of four visits to the clinical site. Informed consent and randomization occurred at visit 1. Testing began at visit 2. 103 patients completed all visits. The following table outlines the demographic information for the trained users who completed all visits.

Demographic	Number	Percent
Total number of users	103	100%
Males	57	55.3%
Females	46	44.7%
Age range (years)	34-86	N/A
Mean age (years)	69	N/A
Age 65-69 years	20	19.4%
Age 70-74 years	23	22.3%
Age 75 years and up	46	44.7%
Educational Level-Some high school through advanced college degree	103	100%
Median Educational level	Some college	N/A
On warfarin 3-12 months	12	11.7%
On warfarin 1-2 years	12	11.7%
On warfarin 3-5 years	23	22.3%
On warfarin >5 years	56	54.4%
Atrial Fibrillation	27	26.2%
Valve replacement	20	19.4%
Stroke/Stroke Prevention	7	6.8%
DVT	3	2.9%
Other heart conditions	22	21.4%
Other clotting disorders	24	23.3%

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Precision	A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained: **User Results** **Professional Results** **N** 296 308 **Mean** 2.47 2.45 **SD** 0.135 0.101 **CV** 5.47 4.12 This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS Plus System.

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 5 2010

Re: k092940
Trade/Device Name: CoaguChek XS Plus PST System
Regulation Number: 21 CFR 864.7550
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: January 26, 2010
Received: January 27, 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,

Geena Philip

for 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

Indication for Use

510(k) Number (if known): K092940

Device Name: **CoaguChek XS Plus System for Patient Self-Testing**

Indication For Use:

The CoaguChek XS Plus System measures blood-clotting time for people who are taking warfarin anticoagulation medications. The CoaguChek XS Plus System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor.

Prescription Use ___XXX___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) K092940