K062925

JAN 29 2007

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: Luann Ochs

Date Prepared: January 29, 2007

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 (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 System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

4) Device Description

The CoaguChek XS is a 3rd generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

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

5) Intended Use

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The 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.

6) Comparison to Predicate Device

The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated 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 self-directed 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 as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. 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 self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.
Precision	A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained: **Patient Results** / **Professional Results** **N** 222 / 257 **Mean** 2.55 / 2.50 **SD** 0.132 / 0.135 **CV** 5.19 / 5.38 This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

ROCHE Diagnostics Corp.
C/O Jennifer Tribbett
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250

JAN 2 9 2007

Re: k062925
Trade/Device Name: CoaguChek® XS System for Patient Self-testing
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: September 27, 2006
Received: September 28, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
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 Part 801), please contact the Office of Compliance at (240) 276-0450. 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/industry/support/index.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

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use

510(k) Number (if known): ~~K060978~~ K062925

Device Name: CoaguChek® XS System for Patient Self-Testing

Indications For Use:

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The 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.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) K062925