



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)
FOLDER: K060978 - 277 pages (FOI:09002143)
COMPANY: ROCHE DIAGNOSTICS (ROCHDIAGD)
PRODUCT: TEST, TIME, PROTHROMBIN (GJS)
SUMMARY: Product: COAGUCHEK XS SYSTEM

DATE REQUESTED: Mar 1, 2011

DATE PRINTED: Mar 25, 2011

Note: Releasable Version



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AUG 11 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

Continued on next page

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

Continued on next page

Performance characteristics

-Continued-

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



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 11 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.

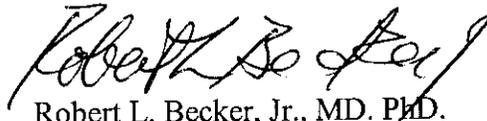
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Page 2 –

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:

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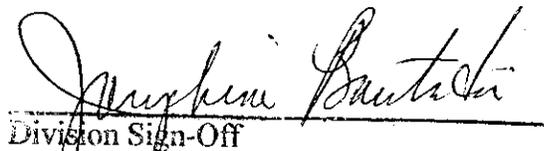
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060978



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

March 19, 2010

Roche Diagnostics
c/o Jennifer Tribbett
9115 Hague Road
Indianapolis, IN 46256 US

Document No: k060978
Re: k060978
Received: April 10, 2006

Categorization Notification

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page <http://www.fda.gov/cdrh/clia>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

If you have any questions regarding this complexity categorization, please contact Lea Carrington at 301-796-6164.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Document Number : k060978

Test System: Roche Diagnostics CoaguChek S System

Analyte : Prothrombin Time (PT)

Complexity : MODERATE

CLIA Routing Slip

Document No : k060978

Re : k060978

Division: DIHD

Branch: HECB

Applicant: Roche Diagnostics

Trade Name: CoaguChek xs system

DMC Date Received: April 10, 2006

Division Date Received: April 11, 2006

Categorization Information

CLIA Reviewer: Valerie Dada [VRD]

Date Review Completed: January 26, 2009

Date Branch Concurred: March 12, 2010

Date Coordinator Concurred:

Effective Date: MAR 19 2010 *g*

Test Systems/Analytes/Grading

(See Attachment)

*PC
3/22*

*PC
JMB*

Document Number : k060978

Test System: Roche Diagnostics CoaguChek S System

Analyte : Prothrombin Time (PT)

Complexity : MODERATE [11]

Knowledge [2]; Training and Experience [2]; Reagents Preparation [1];

Operational Steps [1]; Quality Control [1];

Troubleshooting and Maintenance [2]; Interpretation and Judgment [2]

Rationale : HEM-022

CoaguChek XS PT Test

Cat No. 8425313100
All Test Strips 1 Outer Box

These test strips are to be used with the CoaguChek XS System

Purpose

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 microcoagulated venous whole blood.

Caution: These test strips are for use outside the body only. Do not use the test strips.

Before You Start Testing

If you are new to the CoaguChek XS System, watch the CoaguChek XS System Video and read the CoaguChek XS System Getting Started guide before testing.

Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature or in the refrigerator (2 to 30°C or 36 to 86°F). When stored properly, the test strips can be used until the expiration date printed on the test strip container.

Dispose of the test strips if they are past their "Use By" date.

Handling the Test Strips

When you are ready to test, remove 1 test strip from the container. Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strips. Close the container tightly.

You must use the test strip within 10 minutes of removing it from the container.

Otherwise, you may get an error message and you will have to repeat the test.

Sample Collection and Preparation

This starts the process of collecting a blood sample from a fingertip. Occasionally you may use a capillary tube to collect the fingerstick blood sample. You may also use the CoaguChek XS System to test venous blood. See *Optional Testing Methods* in the CoaguChek XS System User Manual for more information. When collecting any type of sample, follow universal blood collection precautions and guidelines.

Step 1: Getting Ready to Test

Get the supplies:

- CoaguChek XS Meter
- CoaguChek XS PT Test Strip
- Test Strip Code Chip
- Lancet (follow the manufacturer's instructions to prepare the lancet for use)

If you are using test strips from a new, unopened box, you will need to change the Test Strip Code Chip. Use the number code on the test strip container to match the 3 number code on the code chip. To install the code chip, follow the instructions in the Code Chip section of the CoaguChek XS System User Manual.

Put the meter on a flat surface, like a table or countertop, that will not vibrate or move during testing, as this can result in an error message.

Step 2: Testing Blood from a Fingertick

Getting a Good Drop of Blood

Increasing the blood flow in the finger will help you get a good drop of blood. Before you lance the finger, try the following techniques until you see that the fingertip has good color:

- Warm the hand by having the patient hold it under hot or hot soapy water, use a hand warmer, and/or rub the hand with warm water.
- Have the patient hold his or her arm down to the side, so that the hand is below the wrist.
- Massage the finger from its base.
- If needed, immediately after lancing, gently squeeze the finger from its base to encourage blood flow.

Procedure

- 1 Wash the patient's hands with warm, soapy water or wipe the finger with alcohol. Allow the patient's finger to dry completely before performing the fingertick.
- 2 Take a test strip out of the container. Close the container tightly.
- 3 Insert a test strip as far as you can. The meter turns on.
- 4 Confirm that the number displayed matches the number on the test strip container. Then press **OK**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using.
- 5 An hourglass appears as the meter warms up, which takes about 30 seconds.
- 6 When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.
- 7 Use the lancet to perform a fingertick.
- 8 Apply 1 drop of blood to the top or side of the target area. You must apply blood to the test strip within 15 seconds of lancing the finger.
- 9 Do not add more blood. Do not touch or remove the test strip when a test is in progress.
- 10 The result appears in about 1 minute. Record the result.
- 11 Properly dispose of the used lancet and test strip.
- 12 Turn the meter off.

If you need to redo a test, use a new lancet, a new test strip, and a different finger.

Technical Information

How the Test Works

The CoaguChek XS PT Test, used in concert with the CoaguChek XS Meter, will provide an electronic measurement of prothrombin time following initiation of blood coagulation with tissue recombinant thromboplastin. In simple terms, blood reacts with the chemicals in the test strip to create a small electric current in the test strip that measures blood-clotting time.

Contents of the Test Strip

The test strip contains reagent (human recombinant thromboplastin), as well as stabilizers, preservatives, and additives.

Limitations of Procedure

- The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or sera is cannot be used.
- The only plastic syringes without anticoagulants or additives (Gard tubes or syringes) that can be used.
- The blood drop must be a minimum of 10 µl in volume. Low sample volume will cause an error message.
- Never add more blood to test strip after test has begun or perform another test using the same fingertick.
- When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.
- Hematocrit ranges between 25-50% do not significantly affect test results.
- If being performed with the following in vitro spiked samples or animal blood samples (Thyroglobulin) indicated no significant effect on test results:
 - Methionin up to 30 mg/dL
 - Lysine samples containing up to 300 mg/dL of thyroglobulin
 - Benzoyl up to 1000 mg/dL
 - The results are unaffected by heparin concentrations up to 40 U/mL.
 - The CoaguChek XS PT Test is insensitive to low molecular weight heparin (LMWH) up to 2 IU anti-factor Xa activity/mL.
- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA sensitive laboratory method is recommended if the presence of APAs is known or suspected.
- In rare cases, patients with long clotting times (DILINR) may receive an "ERROR" message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

Expected Results

The CoaguChek XS Meter displays test results in units equivalent to International Normalized Ratio measurements. Results may be displayed in the International Normalized Ratio (INR=PT/Normal PT)², seconds, and INR-CL (as it is used rarely by healthcare professionals in Europe).

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparation. Normal INR levels vary from person to person. When the CoaguChek XS PT Test was performed using the CoaguChek XS Meter on 121 normal, healthy, asymptomatic individuals using venous and capillary samples, 87% of the INRs ranged from 0.8 to 1.1, for the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNLPT) has been established as 12 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.

The physician must determine the test INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on Prothrombin Time). Each physician should establish expected values for his or her patient population or individual patients.

Differences in reagents, instruments and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods.

Unusual Results

If the meter displays an error message, refer to the Error Messages section of the CoaguChek XS System User Manual. If the meter displays an unusual test result (other than an error message), check the following items:

- Is the correct code chip in the meter? The 3 number code on the test strip container must match the 3 number code on the code chip.
- Is the meter set up with the correct date and time?

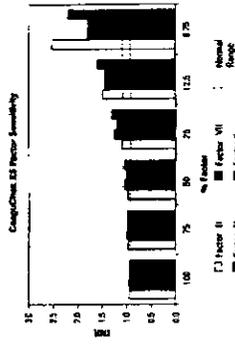
Certain drugs may affect results by affecting warfarin plasma activity. The potential effect of a drug interaction with warfarin or the effect of underlying disease (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.

60
11

Also, changes in the patient's diet can cause variability in test results. Any unusual result should always be followed up with appropriate, comprehensive studies and inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient first to rule out procedural error.

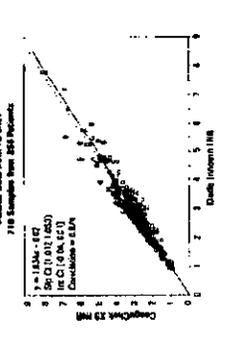
Performance Characteristics

Measuring Range: The CompChek 35 System has a measuring range of 1.1 to 8.8 g/dL. Sensitivity: The CompChek 35 PT test is sensitive to various dietary factors as determined by a pilot study. Single factor dietary changes were combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were compared to the results of the CompChek 35 PT test. The results are shown in the table below. CompChek 35 PT test results in Factors V, VI, VII, and X.



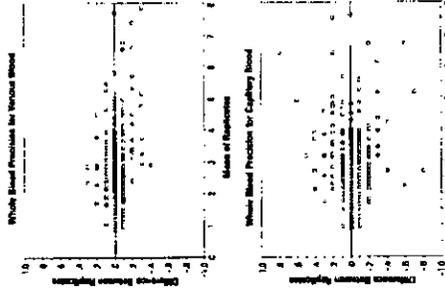
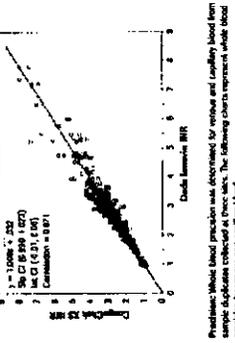
Approximately 110 normal individuals were collected from 800 individuals of three ethnicities. The APTT of each sample was compared to the APTT of a normal plasma sample measured on a Sysmex APTT (APTT) and normal plasma samples were measured on a Sysmex APTT (APTT) and normal plasma samples were measured on a Sysmex APTT (APTT). The results are shown in the table below.

APTT (s)	N	Mean	SD	CV (%)	Correlation
12.0	72	1.178	0.191	16.3	0.913
12.5	78	1.111	0.171	15.4	0.911
13.0	74	0.851	0.123	14.5	0.906



Approximately 700 healthy individuals were collected from 157 individuals of three ethnicities. Capillary blood samples were used on the CompChek 35 (capillary) and the CompChek 35 PT (venous) plasma samples were measured on a Sysmex APTT (APTT) and normal plasma samples were measured on a Sysmex APTT (APTT). The results are shown in the table below.

APTT (s)	N	Mean	SD	CV (%)	Correlation
12.0	238	1.111	0.173	15.6	0.923
12.5	278	1.081	0.168	15.6	0.923
13.0	291	0.897	0.127	14.2	0.921



Built-in Controls and Diagnostic

The CompChek 35 System has built-in control functions integrated into the assay and test menu. It can detect and report quality control test results. The test menu automatically runs the test quality control as part of every blood test. For more information about the built-in quality control functions, see the CompChek 35 System User Manual.

References

1. McA.S. and Dval.T., "Measuring Thrombin Time in Patients with Liver Disease," *Journal of Clinical Investigation* 1977; 79: 177-181.
2. Lottgen.F.A. and von Bismarck.H., "Thrombin Time in Liver Disease: A Review of the Normalization of the Thrombin Time in Liver Disease," *Thrombosis and Haemostasis*, 1981; 55: 148-151.

Return Policy

If there is a problem with the CompChek 35 PT test kit, you may be eligible for a return. Please contact your distributor for more information. For more information, contact your distributor or the following information: 1-800-444-4444, 1-800-444-4444, 1-800-444-4444.

Additional Information

The CompChek 35 System (for manual operation) is not intended for use in the laboratory. It is intended for use in the home. For more information, contact your distributor or the following information: 1-800-444-4444, 1-800-444-4444, 1-800-444-4444.





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 11 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
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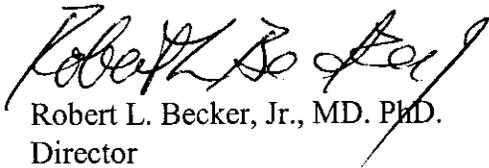
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Sincerely yours,



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:

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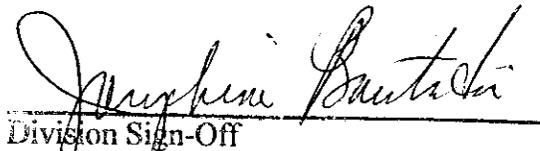
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060978

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 08, 2006

ROCHE DIAGNOSTICS
POINT OF CARE DIAGNOSTICS
9115 HAGUE ROAD
INDIANAPOLIS, IN 46256
ATTN: JENNIFER TRIBBETT

510(k) Number: K060978
Product: COAGUCHEK XS
SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 10, 2006

ROCHE DIAGNOSTICS
POINT OF CARE DIAGNOSTICS
9115 HAGUE ROAD
INDIANAPOLIS, IN 46256
ATTN: JENNIFER TRIBBETT

510(k) Number: K060978
Received: 10-APR-2006
Product: COAGUCHEK XS SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)(b)(4) Write the Payment Identification number on your check.				
<p>A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:</p> <ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 						
<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>ROCHE DIAGNOSTICS CORP 9115 Hague Road P.O. Box 50457 Indianapolis IN 46250-0457 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)</p>		<p>2. CONTACT NAME jennifer tribbett</p> <p>2.1 E-MAIL ADDRESS jennifer.tribbett@roche.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 317-521-3742</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code) NO DATA</p>				
<p>3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)</p> <table border="0"> <tr> <td> <p>Select an application type:</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</p> <p><input type="checkbox"/> Biologics License Application (BLA)</p> <p><input type="checkbox"/> Premarket Approval Application (PMA)</p> <p><input type="checkbox"/> Modular PMA</p> <p><input type="checkbox"/> Product Development Protocol (PDP)</p> <p><input type="checkbox"/> Premarket Report (PMR)</p> </td> <td> <p>3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Original Application</p> <p>Supplement Types:</p> <p><input type="checkbox"/> Efficacy (BLA)</p> <p><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</p> <p><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</p> <p><input type="checkbox"/> 180-day (PMA, PMR, PDP)</p> </td> </tr> </table>			<p>Select an application type:</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</p> <p><input type="checkbox"/> Biologics License Application (BLA)</p> <p><input type="checkbox"/> Premarket Approval Application (PMA)</p> <p><input type="checkbox"/> Modular PMA</p> <p><input type="checkbox"/> Product Development Protocol (PDP)</p> <p><input type="checkbox"/> Premarket Report (PMR)</p>	<p>3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Original Application</p> <p>Supplement Types:</p> <p><input type="checkbox"/> Efficacy (BLA)</p> <p><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</p> <p><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</p> <p><input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>		
<p>Select an application type:</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</p> <p><input type="checkbox"/> Biologics License Application (BLA)</p> <p><input type="checkbox"/> Premarket Approval Application (PMA)</p> <p><input type="checkbox"/> Modular PMA</p> <p><input type="checkbox"/> Product Development Protocol (PDP)</p> <p><input type="checkbox"/> Premarket Report (PMR)</p>	<p>3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Original Application</p> <p>Supplement Types:</p> <p><input type="checkbox"/> Efficacy (BLA)</p> <p><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</p> <p><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</p> <p><input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>					
<p>4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)</p> <p><input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA</p> <p><input checked="" type="checkbox"/> NO, I am not a small business</p> <p>4.1 If Yes, please enter your Small Business Decision Number:</p>						
<p>5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.</p> <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population					
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially					
<p>6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO</p>						
<p>7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)</p> <p>(b)(4)</p>						

Form FDA 8601 (08/2003)

(Close Window)

(Print Cover sheet)

Supplemental pmr - \$ 331 Replacement covers
for #6021956
K35 HE II 49

**Premarket Notification, 510(k)
for Roche Diagnostics
CoaguChek® XS System
Premarket Notification and CLIA Waiver Application**

April 6, 2006

FDA/CDRH/ODE/PHO
2006 APR 10 P 12:11
130017/...

Premarket Notification [510(k)]

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April 6, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluations, Division of Clinical Laboratory Devices
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Premarket Notification and CLIA Waiver Application for the CoaguChek® XS System

Purpose In accordance with 21 CFR 807.81(a)(2), Roche Diagnostics Corporation hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

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.

This premarket notification is being submitted to obtain clearance for the following intended use: This is a CLIA waived system. The CoaguChek XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy.

Our CLIA waiver application is included in section VI. We have no plans to launch the system without waived status; therefore, we respectfully request that the review branch share this submission with your colleagues responsible for complexity categorization.

Continued on next page

A. Device Name Proprietary name: CoaguChek® XS System
Common name: Prothrombin time test
Classification name: Prothrombin time test

B. Establishment registration The CoaguChek XS System (meter and strip) will be manufactured in the Roche Diagnostics facility located in Mannheim Germany. The establishment registration number for this site is 9610126.

C. Classification Regulation Number: 21 CFR 864.7750
Identification: A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

Panel	Classification Number	Class	Classification Name
Hematology	81 GJS	II	Prothrombin time test

D. Performance Standards To date, no performance standards that affect this device have been finalized under Section 514 of the Act.
To the best of our knowledge, FDA has not published a guidance document for review of professional use coagulation assays.

E. Proposed labeling The instructions for use as required by 21 CFR 809.10 are provided in the instrument user's manual and the reagent strip insert. The reagent strips described in this premarket notification can only be used in conjunction with the CoaguChek XS System. We believe our draft labeling satisfies the intent of the regulation.

Continued on next page

F. Substantial equivalence

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). The similarities and differences between the CoaguChek XS System and CoaguChek S System are described in the "New Device vs. Predicate Device" section of this introductory letter.

G. Evaluations Summary

The CoaguChek XS System was evaluated for several performance characteristics, including factor sensitivity, heparin sensitivity, hematocrit effect, whole blood precision, accuracy, reportable and normal range. Actual use situation studies (user studies) were performed in health care professional settings. All of the evaluation studies gave acceptable results compared to the laboratory assay.

H. Software Development Summary

This premarket notification contains information concerning the software utilized to operate this device. This information is based on the August 29, 1991 Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review. A certification statement is enclosed in section V, along with the CoaguChek XS System's hazard analysis which starts on page 172 of this submission.

Predicate Device 510(k) History

The predicate device is the Roche Diagnostics CoaguChek S System.

510(k) Number	Reason for Filing
K994349	Introduce the CoaguChek S System
K020831	Introduce the PT•S (Low ISI) test strip on the CoaguChek S System

Continued on next page

Similarities to predicate device

The CoaguChek XS System is similar to the predicate CoaguChek S System in the following items:

Topic	Comment	
Intended Use	(b) (4)	
Measuring Range		
Closed System		
Specimen collection and preparation instructions		(b)(4)
Sample Volume		
Thromboplastin		
International Sensitivity Index		
Calibration of results		

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	(b) (4)	(b)(4)
Quality Control		
Test Strip Dosing		
Start up		
Memory		

Continued on next page

Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek XS System and the CoaguChek S System. Data to support these claims for the CoaguChek XS System are included in section IV of this 510(k) submission.

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

Continued on next page

Performance characteristics

-Continued-

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

Continued on next page

CLIA Waiver

(b) (4)

(b)(4)

Confidentiality request

Roche Diagnostics requests that FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

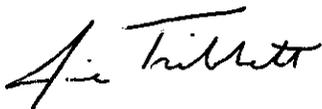
Closing

We trust the information provided in this Premarket Notification [510(k)] will support a determination of substantial equivalence of the CoaguChek XS System, to other prothrombin time test systems currently marketed in the United States.

If you should have questions or require further information, please do not hesitate to contact this office.

- Phone: (317)-576-3742
- FAX: (317) 576-2324

Sincerely,



Jennifer Tribbett
Regulatory Affairs Principal

enclosures

PREMARKET SUBMISSION COVER SHEET

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission April 6, 2006	User Fee Payment ID Number MD6023465-956733	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Roche Diagnostics		Establishment Registration Number (if known) 1823260	
Division Name (if applicable) Int of Care Diagnostics		Phone Number (including area code) (317) 521-3742	
Street Address 9115 Hague Road		FAX Number (including area code) (317) 521-2324	
City Indianapolis	State / Province IN	ZIP/Postal Code 46256	Country USA
Contact Name Jennifer Tribbett			
Contact Title Regulatory Affairs Principal		Contact E-mail Address Jennifer.tribbett@roche.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	GJS	2		3	
		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K994349	1	CoaguChek S System	1	Roche Diagnostics
2	K020831	2	PT•S (Low ISI) test strip on the CoaguChek S System	2	Roche Diagnostics
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Prothrombin time test

	Trade or Proprietary or Model Name for This Device		Model Number
1	CoaguChek® XS System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	K994349	2	K020831	3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code GJS	C.F.R. Section (if applicable) 21 CFR 864.7750	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Hematology		

Indications (from labeling)

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.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 9610126		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Roche Diagnostics GmbH			Establishment Registration Number 9610126		
Division Name (if applicable) Point of Care Diagnostics			Phone Number (including area code) (317) 521-3742 (in the U.S.)		
Street Address Sandhofer Strasse 116			FAX Number (including area code) (317) 521-2324 (in the U.S.)		
City Mannheim		State / Province	ZIP/Postal Code D-68298	Country Germany	
Contact Name Jennifer Tribbett (in the U.S.)		Contact Title Regulatory Affairs Principal		Contact E-mail Address Jennifer.tribbett@roche.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

15

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
 ** - Required for Class III devices, only.
 *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: Cardiac D-Dimer Assay: CoaguChek XS System					K		
Submitter (Company): Roche Diagnostics							
Items which should be included (circle missing & needed information)	S P E C I A L		A B B R E V I A T E D		T R A D I T I O N A L		√ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	<input checked="" type="checkbox"/> YES	NO	
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"							
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							
Go to # 2,4		Go to 3,4,5		Go to # 4, 5		Page 1	
2. "SPECIALS" – ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) STATEMENT – INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				*If no – STOP not a special			
c) STATEMENT – FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*				*If no – STOP not a special			
d) Design Control Activities Summary							
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.							
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.							
iii) A declaration of conformity with design controls. The declaration of conformity should include:							

<p>1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(a) and the results demonstrated that the predetermined acceptance criteria were met.</p>				
<p>2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.</p>				

→ → → **CONTINUE TO SECTION 4** ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		√ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance Document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type.							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, That all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed.							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

4. GENERAL INFORMATION; REQUIRED IN ALL 510(K) SUBMISSIONS

√ IF ITEM IS

							NEEDED AND IS MISSING
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) Trade name, classification name, establishment registration number, address of manufacturer, device class					X		Page 4
b) OR a statement that the device is not yet classified	FDA – may be a classification request; see coordinator						
c) Identification of legally marketed equivalent device		NA			X		Page 5
d) Compliance with Section 514 – performance standards		NA			X		Page 4
e) Address of manufacturer					X		Page 14
f) Truthful and Accurate Statement					X		Page 25
g) Indications for Use enclosure					X		Page 26
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					X		Page 29
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					X		Pages 3-8
k) Proposed Labeling:					X		Page 214
i) Package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
iv) MRI compatibility (if claimed)							
m) Comparison information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					X		Pages 6-8
i) labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing		NA					
vi) safety characteristics		NA					
n) If kit, kit certification						NA	
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/ formulation:						NA	
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							

b) Sterilization and expiration dating information-							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) radiation dose							
c) Software validation & verification					X		Page 146
i) hazard analysis					X		Page 172
ii) level of concern					X		Page 150
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening _____ Yes _____ no

Reviewer: _____

Date: _____

Concurrence by Review

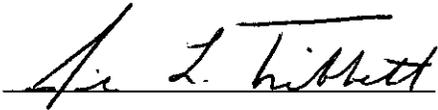
Branch: _____

Premarket Notification

Truthful and Accurate Statement

As required by 21 CFR 807.87:

I certify, in my capacity as Regulatory Affairs Principal for Roche Diagnostics, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in black ink, appearing to read "Jennifer L. Tribbett", written over a horizontal line.

Jennifer L. Tribbett, RAC

April 6, 2006

74 25

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

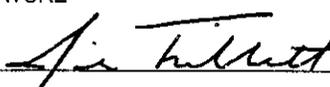
With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate) submitted in support of this application. I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigator	(b) (6)	
	(b)(6)	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	Jennifer Tribbett	TITLE	Regulatory Affairs Principal
FIRM/ORGANIZATION	Roche Diagnostics Corporation		
SIGNATURE		DATE	April 6, 2006

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

510(k) Summary

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

Continued on next page

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

Continued on next page

Performance characteristics

-Continued-

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

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.

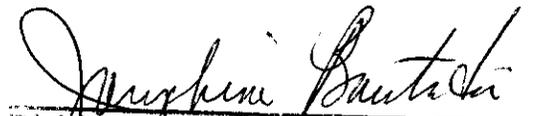
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060978

Performance Claims

External Site Information

(b) (4)

(b)(4)

Factor Sensitivity

Pages 59 through 61 redacted for the following reasons:

Study Data, b4

Heparin Sensitivity

Pages 63 through 82 redacted for the following reasons:

Technical Data, b4

Hematocrit

Hematocrit (HCT) Effect

Overview

An internal hematocrit (HCT) study was performed in order to establish the HCT range for the PT test strip on the CoaguChek XS System.

**Acceptance
criteria**

(b)(4)

**Protocol
Summary**

(b)(4)

Conclusion

Continued on next page

Pages 85 through 90 redacted for the following reasons:

Study Data, b4

Interferences

Pages 92 through 102 redacted for the following reasons:

Study Data, b4

Normal Range Study

Executive Summary for the Normal Range Study

Summary

(b) (4)

Testing site location

(b)(4)

Study design

Pages 105 through 130 redacted for the following reasons:

Study Data, b4

Test Strip Stability

Test Strip Stability

Overview

(b)(4)

**Acceptance
Criteria**

**Protocol
Summary**

(b)(4)

Conclusion

Continued on next page

Pages 133 through 144 redacted for the following reasons:

Study Data, b4

Quality Control

On-board (built-in) Quality Control

**On-Board
Quality Control
(OBC)**

(b) (4)

(b)(4)

**Protocol
Summary**

Pages 147 through 160 redacted for the following reasons:

Study Data, b4

Instrument Failsafes

Automatic Meter Checks (Failsafes)

Meter Failsafes

(b) (4)

(b)(4)

Failsafe List

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

Calibration

Calibration

Traceability of calibration

(b) (4)

(b)(4)

Original Calibration

(b) (4)

(b)(4)

(b)(4)

(b)(4)

Software Development Summary



Diagnostics

510(k) Software Development Summary

Roche CoaguChek XS
(PT Monitoring System)

Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany

Recorder:
Filed in Dept.:
Date:

(b) (4)

(b)(4)

(b) (2) Low

(b)(2)Low

1/18

196

149

Pages 171 through 187 redacted for the following reasons:

Software Development, b4

K060978

CLIA WAIVER APPLICATION

CLIA Waiver Application: Introduction

Purpose

(b) (4)

**Rationale for
waived status
request**

(b)(4)

Pages 190 through 194 redacted for the following reasons:

Technical Data, b4



Risk Management Summary File

(b) (4)
(b)(4)

Procedure

(b) (4)

(b)(4)

Pages 196 through 236 redacted for the following reasons:

Technical Data, b4

New Device Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Valerie A. Doba
Subject: 510(k) Number K060978/SI

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices-
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

Truthful and Accurate Statement Requested Enclosed

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

655 II 21 CFR 804.7750

Review: Josephine Santurda 8140 8/9/06
(Branch Chief) (Branch Code) (Date)

Final Review: Edith Baker 10 Aug 2006
(Division Director) (Date)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 060978

Reviewer: VALERIE R. DADA

Division/Branch: DIHD

Device Name: ROCHE DIAGNOSTICS COAGUCHEK® XS SYSTEM

Product To Which Compared (510(K) Number If Known): ROCHE DIAGNOSTICS COAGUCHEK S SYSTEM (K020831)

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

1. **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.
2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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

(b)(4), (b)(5)

(b)(4), (b)(5)

5. **Describe the new technological characteristics:** The CoaguChek® XS System

(b)(4), (b)(5)

(b)(4), (b)(5)

by the CoaguChek XS System.

6. **Explain how new characteristics could or could not affect safety or effectiveness:** The technological characteristics of the CoaguChek® XS System does not affect safety or effectiveness because it measure the same endpoint as the predicated device, and it is technology that is utilized by a legally marketed device.
7. **Explain how descriptive characteristics are not precise enough:** Descriptive characteristics are not precise enough because (b)(4), (b)(5) (5)

(b)(4), (b)(5)

(b)(4), (b)(5)

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:** Performance data demonstrated that the device is substantially equivalent to a legally marketed device.

Precision was evaluated by (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

The accuracy study (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

Along with software validation documentation, the submission included factor sensitivity, heparin sensitivity, hematocrit effect, reportable range, and normal range data.

All studies demonstrated acceptable performance.

Valerie A. Dada
8/9/06

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

K060978

B. Purpose for Submission:

Clearance of a new instrument and test strip

C. Measurand:

Prothrombin Time

D. Type of Test:

Electrochemical

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

CoaguChek® XS System

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7750

2. Classification:

Class II

3. Product code:

GJS

4. Panel:

H. Intended Use:

1. Intended use(s):

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.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The CoaguChek® XS System includes a meter and CoaguChek® XS PT test strips. The test strip contains a human recombinant tissue factor, and is calibrated to an ISI of 1.0.

The test strip incorporates quality control material that accesses strip integrity.

The CoaguChek® XS meter automatically stores up to 100 test results along with their dates and times in memory.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Diagnostics CoaguChek S System

2. Predicate 510(k) number(s):

K020831

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Quantitative prothrombin time (PT) using fresh capillary or non-anticoagulated venous whole blood	same
Measuring Range	0.8- 8.0 INR	Same
Sample Volume	10 µl	same
Reagent	Human recombinant thromboplastin	same

Differences		
Item	Device	Predicate
Technology	Electrochemical with amperometric detection of thrombin activity	Optical detection of thrombin activity
Quality Control	On-board integrated QC which detects test strip integrity	External liquid controls and electronic quality control
Test Strip Dosing	Top and side dosing	Top dosing only
Memory	100 test results with time and date	60 test results with time and date

K. Standard/Guidance Document referenced (if applicable):

NCCLS/CLSI Document C28-A, "How to Define and Determine Reference Intervals"

L. Test Principle:

When a blood sample is applied to the test strip, thromboplastin activates the coagulation cascade which leads to the formation of thrombin. Thrombin cleaves the thrombin substrate creating an electrochemically active peptide, which generates an electrical signal. The signal is converted to an INR value and displayed by the CoaguChek XS System.

The on-board quality control is a bi-level control that accesses test strip integrity. The PT test and QC testing are performed simultaneously. The test system determines whether the quality control is within preset limits. If it is, the meter displays a short term "QC✓", and then the PT test result. If the QC is not within limits, the meter displays "error QC", and no PT test result will be displayed.

M. Performance Characteristics (if/when applicable):

Pages 246 through 248 redacted for the following reasons:

Technical Data, b4

The CoaguChek XS System incorporates a bi-level on-board quality control (OBC) within the CoaguChek XS test strip that monitors test strip integrity.

Level 1 OBC detects strip defects such as reagent defects, capillary compression and electrode defects. Level 2 OBC directly measures strip damage due to such things as exposure to increased humidity, light, and temperature.

The pre-determined OBC ranges are programmed into the lot specific code chip that is packaged with the matching test strip lot.

Acceptable data was presented validating the OBC.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the “Performance Characteristics” Section above:

An instrument failsafe checklist was presented outlining the QC check made by the CoaguChek XS meter.

Q. Proposed Labeling:

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

R. Conclusion:

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

S. Other Supportive Device and Instrument Information:

T. Administrative Information:

1. Applicant Contact Information:

a. *Name of applicant:*

Roche Diagnostic

b. *Mailing address:*

9115 Hague Road

Indianapolis, IN 46256

c. *Phone #:*

317-521-3742

d. *Fax #:*

317-521-2324

e. *E-mail address (optional):*

Jennifer.tribbett@roche.com

f. *Contact:*

Jennifer Tribbett

2. Review Documentation:

10 Apr 2006

Submission received in DMC

11 Apr 2006

Submission received in OIVD

7 Jun 2006

Submission placed on hold

7 July 2006

Supplemental information received in DMC

10 July 2006

Submission received I OIVD

9 Aug 2006

SE

U. Reviewer Name and Signature:

A handwritten signature in black ink, appearing to read "Valerie R. Dada", written over a horizontal line.

Valerie R. Dada
CDRH/OIVD/DIHD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Valerie R. DeDa
Subject: 510(k) Number K060978
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 day

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: _____ (Branch Chief) _____ (Branch Code) _____ (Date)

Final Review: _____ (Division Director) _____ (Date)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Devices and Radiologic Health

Date: 7 June 2006

MEMORANDUM

To: FILE K060978
COAGUCHEK XS
ROCHE DIAGNOSTICS

Subject: Request for additional information

From: Valerie R. Dada, DIHD Reviewer *VD*

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

The CoaguChek XS System includes a meter and test strips. The test strips are made of

(b)(4)

(b)(4)

Dada, Valerie

From: Dada, Valerie
Sent: Wednesday, June 07, 2006 5:59 AM
To: 'Tribbett, Jennifer'
Subject: K060978- CoaguChek XS System

Hi Jennifer;

We have reviewed the information you submitted for the CoaguChek XS System, and we have the following concerns:

1. (b)(4), (b)(5)

(b)(4), (b)(5)

2.

This submission will be placed on hold pending receipt of the requested additional information. Please respond to the issues in writing to the

Document Mail Center (HFZ-401)
9200 Corporation Blvd
Rockville, MD 20850.

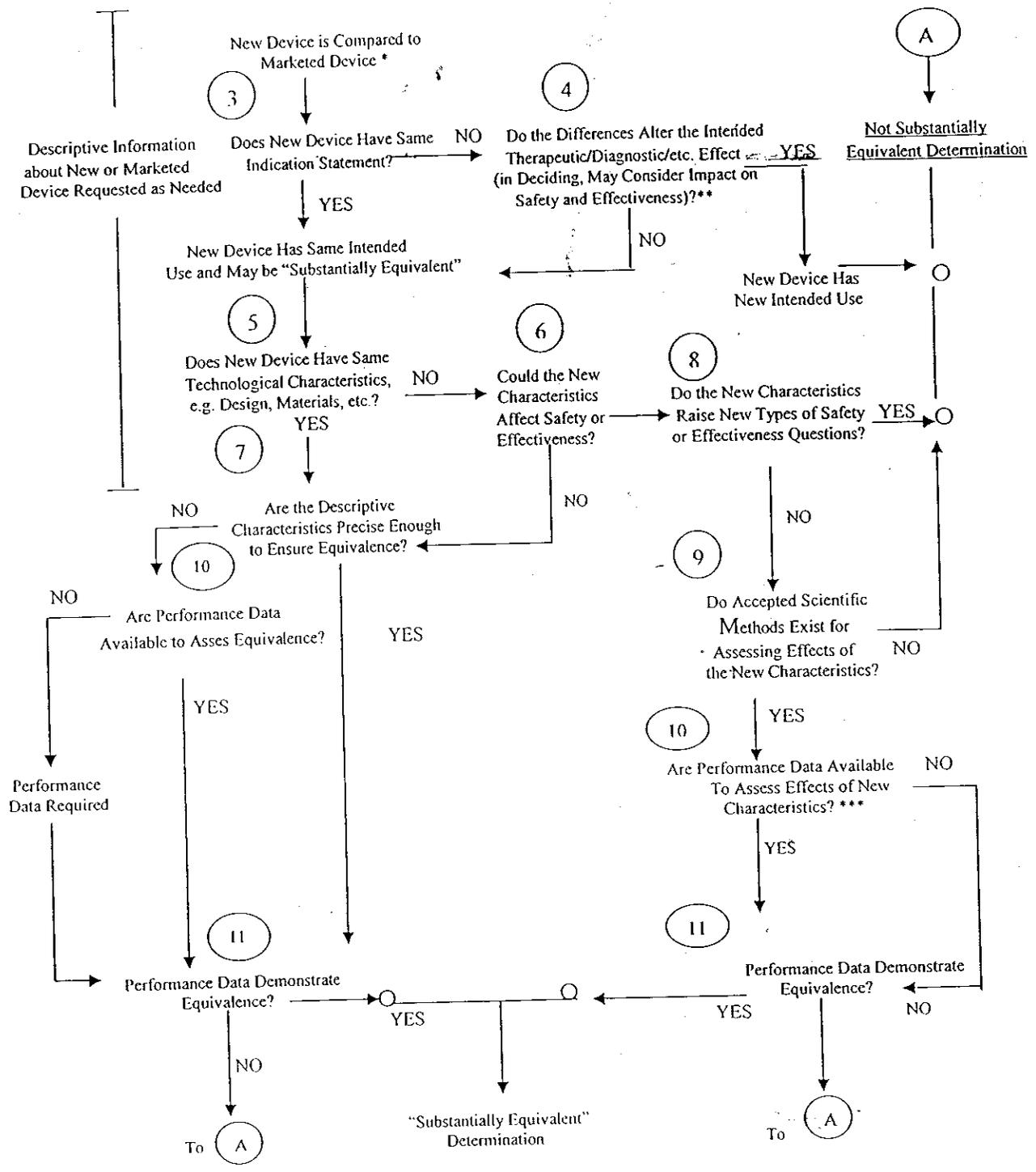
Please feel free to contact me if you have any questions.

Sincerely,

Valerie R. Dada
Scientific Reviewer
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
(240) 276-0443, X162
fax: (240) 276-0663

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- * 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

5

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No
 Reviewer: _____
 Concurrence by Review Branch: _____
 Date: _____

7

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

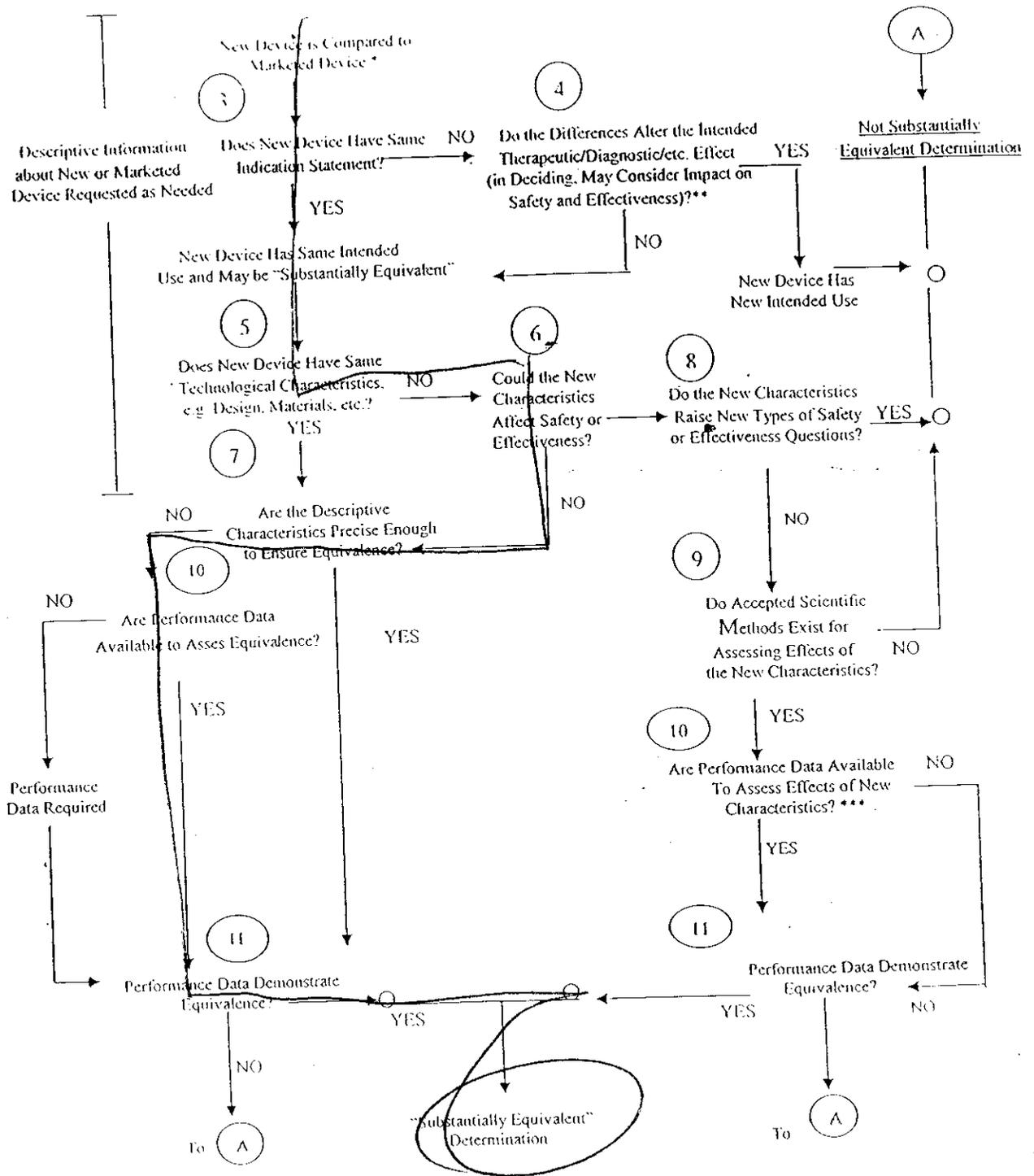
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 07, 2006

ROCHE DIAGNOSTICS
POINT OF CARE DIAGNOSTICS
9115 HAGUE ROAD
INDIANAPOLIS, IN 46256
ATTN: JENNIFER TRIBBETT

510(k) Number: K060978
Product: COAGUCHEK XS
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



K060978/S1

Diagnostics

July 5, 2006

Ms. Valerie Dada
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

CoaguChek XS System (K#060978) – response to FDA’s e-mail message dated June 7, 2006

Background The CoaguChek XS System was submitted to FDA under K#060978 on April 10, 2006. On June 7, 2006 you sent an e-mail with two concerns.

This letter addresses those concerns.

**June 7, 2006
(e-mail)**

Concern #1

(b)(4), (b)(5)

**Response
Concern #1**

(b)(4), (b)(5)

21 K5 1

**Response
Concern #1**

-continued-

(b)(4), (b)(5)

(b)(4), (b)(5)

**Response
Concern #1**

-continued-

(b)(4), (b)(5)

(b)(4), (b)(5)

**Response
Concern #1**

-continued-

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

Pages 271 through 274 redacted for the following reasons:

Technical Data, b4

Concern # 2

(b)(4), (b)(5)

Response to concern #2

(b)(4), (b)(5)

Closing

We would like to thank you for the quick review of our submission. We are very excited about the enhancements our next generation coagulation system offers to our customers, and we look forward to marketing this system in the near future.

We believe the responses found in this letter have addressed your concerns. Therefore, we hope the outcome from this response letter is a determination of substantial equivalence.

Thank you again for your timely response. If you have any additional questions, please feel free to contact me.

- Phone: (317) 521-3742
- FAX: (317) 521-2324

Sincerely,



Jennifer Tribbett
Regulatory Affairs Principal

Attachment I

CoaguChek[®] XS PT Test

Call the 24x7x365 Helpline at 1-800-441-1100



These test strips are to be used with the CoaguChek XS System.

Purpose

The CoaguChek XS System is intended for use by professional healthcare providers for the point-of-care measurement of prothrombin time (PT) for the monitoring of warfarin therapy. The CoaguChek XS System uses fresh capillary or non-anticoagulated venous whole blood.

Caution: These test strips are for use outside the body only. Do not cut the test strips.

Before You Start Testing

If you are new to the CoaguChek XS System, watch the CoaguChek XS System Video and read the CoaguChek XS System Getting Started guide before testing.

Storing the Test Strips

Store the test strips in their container, with the cap closed, with the container in a cool, dry room temperature or air refrigeration (2 to 30°C or 36 to 86°F) until the use-by date. The test strips can be used until the expiration date printed on the test strip container. Dispose of the test strips if they are past their "Use By" date.

Handling the Test Strips

When you are ready to test, remove 1 test strip from the container. Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strips. **Close the container tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

Sample Collection and Preparation

The steps that follow apply to collecting a blood sample from a fingertip. Optionally, you may use a capillary tube to collect the fingertip blood sample. You may also use the CoaguChek XS System to test venous blood. See *Optional Testing Methods* in the CoaguChek XS System User Manual for more information. When collecting any type of sample, follow universal blood collection precautions and guidelines.

Step 1: Getting Ready to Test

Gather supplies:

- CoaguChek XS Meter
- Test Strip Code Chip
- Lancet (follow the manufacturer's instructions to prepare the lancet for use.)

If you are using test strips from a new, unopened box, you will need to change the Test Strip Code Chip. The 3-number code on the test strip container must match the 3 number code on the code chip. To install the code chip, follow the instructions in the Code Chip section of the CoaguChek XS System User Manual.

Put the meter on a flat surface, like a table or counter-top, that will not vibrate or move during testing, as this can result in an error message.

Step 2: Testing Blood from a Fingertip

Getting a Good Drop of Blood
Increasing the blood flow in the finger will help you get a good drop of blood. Before you lance the finger, try the following techniques until you see that the fingertip has good color:

- Warm the hand by having the patient hold it under his or her armpit, use a hand warmer, and/or wash the hand with warm water.
- Have the patient hold his or her arm down to the side, so that the hand is below the wrist.
- Massage the finger from its base.
- If needed, immediately after lancing, gently squeeze the finger from its base to encourage blood flow.

Procedure

1. Wash the patient's hands with warm, soapy water or wipe the finger with alcohol. Allow the patient's finger to dry completely before performing the fingerstick.
 2. Take a test strip out of the container. **Close the container tightly.**
 3. Insert a test strip as far as you can. The meter turns on.
 4. Confirm that the number displayed matches the number on the test strip container. Then, for the first time you use the meter, make sure you are using the code chip that came with the test strips you are using.
 5. An hourglass appears as the meter warms up, which takes about 60 seconds.
 6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.
 7. Use the lancet to perform a fingerstick.
 8. Apply 1 drop of blood to the top or side of the target area. You must apply blood to the test strip within 15 seconds of lancing the finger.
 9. Do not add more blood. Do not touch or remove the test strip when a test is in progress.
 10. The result appears in about 1 minute. Record the result.
 11. Properly dispose of the used lancet and test strip.
 12. Turn the meter off.
- If you need to redo a test, use a new lancet, a new test strip, and a different finger.

Technical Information

How the Test Works

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Meter, will provide an electrochemical measurement of prothrombin time (following activation of blood coagulation with human recombinant thromboplastin, in simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time).

Contents of the Test Strip

The test strip contains reagent (human recombinant thromboplastin), as well as stabilizers, preservatives, and additives.

Limitations of Procedure

- The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
- Use only plastic syringes without anticoagulants or additives. Glass tubes or syringes must not be used.
- The blood drop must be a minimum of 10 µl in volume. Low sample volume will cause an error message.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous (IV) iron therapy, do not collect sample from arm receiving the infusion line.
- Hematocrit ranges between 25-55% do not significantly affect test results.
- Testing performed with the following 7 other blood samples or names blood samples (Erythrocytes) appeared to significantly affect on test results:
 - Blotting up to 20 mg/dL of urine
 - Hemolysis up to 1000 mg/dL
 - Hemolysis up to 1000 mg/dL
- The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor IIa activity/mL.
- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e. elevated INR values. A comparison to an APAs sensitive laboratory method is recommended if the presence of APAs is known or suspected.
- In rare cases, patients with long clotting times (SLT) may receive an "ERR08: 7" display. A bit error message appears again when the test is repeated. The result must be checked using another method.

Expected Results

The CoaguChek XS Meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the International Normalized Ratio (INR) (0.8 to 1.2), seconds, and % Clotting Time (and finally by healthcare professionals in Europe).

Each lot of test strips is calibrated to a reference lot that is specific to the INR. When the CoaguChek XS PT Test was performed using the CoaguChek XS Meter on 121 normal, healthy, weight-average individuals using various and capillary samples, 97% of the INRs ranged from 0.8 to 1.1 for the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 12 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.

The physician must determine the test INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment. The test results are not intended to be used to adjust treatment orders for the or other patient population or individual patients. Differences in reagent, instruments, and/or analytical variables can affect cross-lot comparisons. These factors should be considered when comparing different point-of-care test methods.*

Unusual Results

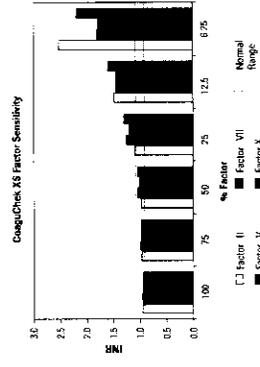
If the meter displays an error message, refer to the Error Message section of the CoaguChek XS System User Manual. If the meter displays an unusual test result (other than an error message), check the following items:

- Is the correct code chip in the meter? The 3-number code on the test strip container must match the 3 number code on the code chip.
 - Is the meter set up with the correct date and time?
- Certain drugs may affect results by affecting warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.

Also, changes in the patient's diet can cause unusually low or high results. Any unusual results should always be followed up with appropriate, guideline studies and inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

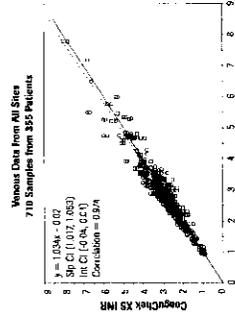
Performance Characteristics

Measuring Range: The CoagChek XS System has a reportable range of 0.8 to 8.0 INR. Sensitivity: The CoagChek XS PT Test is capable of precise clotting factors at plasma levels. Specific factor abnormal plasma was combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were then tested using three representative lots of the CoagChek XS PT Test across sixteen CoagChek XS meters. The results, as seen in the graph below, represent the typical CoagChek XS PT Test accuracy to factors II, V, VII, and X.



Accuracy: 710 venous samples were collected from 355 outpatients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample measured on a Sysmex Analyzer using Dade Immobin (SI = 1.02). The patient clinical conditions included (Number of patients): normal (82), renal fibrosis (174), valve replacement (89), stroke (25), DVT (16), other heart-related disorders (6), some clotting disorders (8), other (6).

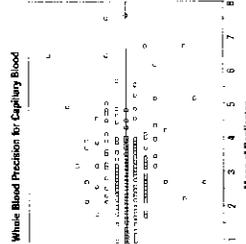
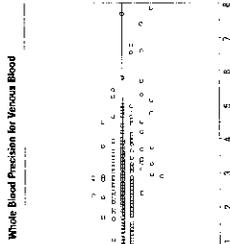
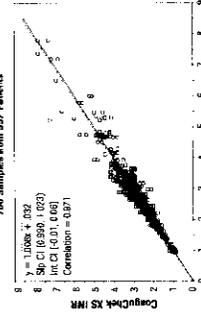
Site	N	Slope	Intercept	Correlation
Site 1	737	1.05	-0.10	0.973
Site 2	230	1.11	-0.11	0.971
Site 3	248	0.984	-0.02	0.985
All	710	1.034	-0.02	0.974



Precision: Whole blood precision was determined for venous and capillary blood from sample duplicates collected at three sites. The following charts represent whole blood precision for venous and capillary blood.

Accuracy: 710 capillary samples were collected from 357 outpatients at three external sites. Capillary blood samples were assayed on the CoagChek XS meter with the CoagChek XS PT Test and venous plasma samples were measured on a Sysmex Analyzer with Dade Immobin (SI = 1.02). The results comparison is as follows:

Site	N	Slope	Intercept	Correlation
Site 1	230	1.11	-0.10	0.973
Site 2	229	1.03	-0.08	0.979
Site 3	241	0.92	0.02	0.985
All	700	1.006	0.02	0.974



Built-In Controls and Diagnostics

The CoagChek XS System has quality control functions integrated into the meter and test strips, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every test. For more information about the built-in quality control functions, see the CoagChek XS System User Manual.

References

1. Mol, S and Ortel, T.L. "Measuring Warfarin Therapy in Patients with Lupus Anticoagulants." *Annals of Internal Medicine* 1997; 127: 177-183.
2. Leongitragul, FA, van den Besouw, A.M.P. and Lewis, S.M. "Reliability and Clinical Impact of the Normalization of the Prothrombin Time in Oral Anticoagulant Control." *Thromb Haemostas*, 1995; 53: 148-154.

Return Policy

If there is a problem with the CoagChek XS PT Test Strip, you may be asked to return the meter with the test strip. CoagChek XS PT Test Strips are not returnable. Call Roche Diagnostics Technical Service Center at 1-800-429-4674. You will be mailed a return authorization label which must be put on the shipping carton.

Additional Information

The CoagChek XS System User Manual contains more information. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-429-4674, 24 hours a day, 7 days a week.

The following U.S. patents have been granted or are pending for the CoagChek XS System: 6,898,452; 6,898,453; 6,898,454; 6,898,455; 6,898,456; 6,898,457; 6,898,458; 6,898,459; 6,898,460; 6,898,461; 6,898,462; 6,898,463; 6,898,464; 6,898,465; 6,898,466; 6,898,467; 6,898,468; 6,898,469; 6,898,470; 6,898,471; 6,898,472; 6,898,473; 6,898,474; 6,898,475; 6,898,476; 6,898,477; 6,898,478; 6,898,479; 6,898,480; 6,898,481; 6,898,482; 6,898,483; 6,898,484; 6,898,485; 6,898,486; 6,898,487; 6,898,488; 6,898,489; 6,898,490; 6,898,491; 6,898,492; 6,898,493; 6,898,494; 6,898,495; 6,898,496; 6,898,497; 6,898,498; 6,898,499; 6,898,500; 6,898,501; 6,898,502; 6,898,503; 6,898,504; 6,898,505; 6,898,506; 6,898,507; 6,898,508; 6,898,509; 6,898,510; 6,898,511; 6,898,512; 6,898,513; 6,898,514; 6,898,515; 6,898,516; 6,898,517; 6,898,518; 6,898,519; 6,898,520; 6,898,521; 6,898,522; 6,898,523; 6,898,524; 6,898,525; 6,898,526; 6,898,527; 6,898,528; 6,898,529; 6,898,530; 6,898,531; 6,898,532; 6,898,533; 6,898,534; 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6,898,626; 6,898,627; 6,898,628; 6,898,629; 6,898,630; 6,898,631; 6,898,632; 6,898,633; 6,898,634; 6,898,635; 6,898,636; 6,898,637; 6,898,638; 6,898,639; 6,898,640; 6,898,641; 6,898,642; 6,898,643; 6,898,644; 6,898,645; 6,898,646; 6,898,647; 6,898,648; 6,898,649; 6,898,650; 6,898,651; 6,898,652; 6,898,653; 6,898,654; 6,898,655; 6,898,656; 6,898,657; 6,898,658; 6,898,659; 6,898,660; 6,898,661; 6,898,662; 6,898,663; 6,898,664; 6,898,665; 6,898,666; 6,898,667; 6,898,668; 6,898,669; 6,898,670; 6,898,671; 6,898,672; 6,898,673; 6,898,674; 6,898,675; 6,898,676; 6,898,677; 6,898,678; 6,898,679; 6,898,680; 6,898,681; 6,898,682; 6,898,683; 6,898,684; 6,898,685; 6,898,686; 6,898,687; 6,898,688; 6,898,689; 6,898,690; 6,898,691; 6,898,692; 6,898,693; 6,898,694; 6,898,695; 6,898,696; 6,898,697; 6,898,698; 6,898,699; 6,898,700; 6,898,701; 6,898,702; 6,898,703; 6,898,704; 6,898,705; 6,898,706; 6,898,707; 6,898,708; 6,898,709; 6,898,710; 6,898,711; 6,898,712; 6,898,713; 6,898,714; 6,898,715; 6,898,716; 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