OCT 2 4 2002

K020831

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.
P.O. Box 50457
Indianapolis, IN 46250-0457

Contact Person: Jennifer Tribbett

Date Prepared: October 22, 2002

2) Device name

Proprietary name: PT•S Test Strips and Controls for the CoaguChek S System

Common name: Prothrombin time test

Classification name: Prothrombin time test

3) Predicate device

We claim substantial equivalence to International Technidyne Corporation's (ITC) ProTime Microcoagulation System- ProTime 3 Cuvette (K010599)

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4) Device Description

The PT•S test strip is intended for quantitative prothrombin time (PT) testing for monitoring of warfarin therapy, using fresh capillary or non-anticoagulated venous whole blood with the CoaguChek S System by professional health care providers.

Blood coagulation is one of the body's protective responses. Blood clots (thrombi) form as a direct response to vessel injury, preventing excessive loss of blood. Certain disease conditions require oral anticoagulants, sometimes known as blood thinners. Warfarin, sometimes known as Coumadin®, is a commonly used anticoagulant. Patients on warfarin must be carefully monitored to ensure the anticoagulant level is maintained in the therapeutic range. One method for monitoring the anticoagulant level is by using the one-stage Prothrombin Time (PT) Test. The PT•S test strip uses a modified version of this method.

The PT•S test strip, used as directed with the CoaguChek S monitor, will accurately measure blood PT values. After placing a drop of fresh whole blood on the test strip, the blood is drawn into the reaction chamber and mixed with reagents that cause coagulation to begin. In the test strip, tiny iron particles are mixed with the sample. Alternating magnetic fields cause the iron particles to move within the sample. The endpoint is reached when the blood clot stops the iron particles from moving. The PT result is then displayed by the monitor.

5) Intended use

For quantitative prothrombin time (PT) testing for monitoring of warfarin therapy, using fresh capillary or non-anticoagulated venous whole blood by professional health care providers.

6) Comparison to predicate device

The Roche Diagnostics PT•S test strip and controls for the CoaguChek S System are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, the PT•S test strip and controls are substantially equivalent to International Technidyne Corporation's (ITC) ProTime Microcoagulation System- ProTime 3 Cuvette (K010599).

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Similarities to predicate device

The PT•S test strip and controls are similar to the ITC ProTime System in the following items:

Topic	ProTime Microcoagulation System (K010599) As Indicated in the ProTime Device Insert	PT•S Test Strips For Use With CoaguChek S System
Intended Use	For the quantitative determination of prothrombin time from fingerstick whole blood or anticoagulant-free venous whole blood. Intended for professional use in the management of patients treated with oral anticoagulants.	For the quantitative prothrombin time (PT) testing for monitoring of warfarin therapy, using fresh capillary or non-anticoagulated venous whole blood by professional health care providers.
Test Principle	Measures the PT using fibrin clot formation and detection.	Same
Reagents	Sensitive recombinant thromboplastin with an ISI of approximately 1.0.	Same

Differences from predicate device

The key difference between the PT•S test strip and the ProTime Microcoagulation System is the location of the Quality Controls. Both systems offer quality controls that satisfy the same function and requirements. However, the ProTime System utilizes quality controls which are built into the reagent cuvette, where the Roche PT•S test strip utilizes external liquid controls.

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Performance characteristics

The following chart shows a comparison of performance characteristics for the PT•S test strip and the ProTime Microcoagulation System.

Claim	ProTime Microcoagulation System (K010599) As Indicated in the ProTime Device Insert	PT•S Test Strips For Use With CoaguChek S System
Normal Range	Not Indicated in the ProTime Insert.	When the PT•S test was performed using the CoaguChek S monitor on 122 normal, healthy, warfarin-free individuals using venous and capillary samples, 99% of the venous and capillary INRs ranged from 0.8 to 1.1.
Reportable Range	INR range of 0.8 to 7.0 with a calculated INR from 0.8 to 9.9. If INR >7.0, the numerical result is marked with an "*". If INR >9.9 a message indicating this is displayed. NOTE: The ProTime gives a **numerical** result up to **9.9** INR.	The CoaguChek S System has a PT reportable range of 0.8 – 6.0 INR.
Factor Sensitivity	ProTime is sensitive to deficiencies in vitamin K-dependent coagulation factors known to influence the PT test (ie. Factors II, VII and X)	Internal studies were performed utilizing four replicates of each Factor Level (II, V, VII and X). Samples were assayed on the CoaguChek S and Ortho Recombiplastin on the MLA 900 Analyzer. Results are shown as graphs in the test strip insert.
Hematocrit Range	Hematocrit levels between 20% and 60% do not significantly affect test results.	Hematocrit ranges between 32-52% do not significantly affect test results.
Heparin Levels	Results may be affected in patients receiving heparin or who have an abnormal response to heparin.	The results are unaffected by heparin concentrations up to 2.0 U/mL. The PT•S test strip is insensitive to low molecular weight heparins up to 1 IU anti-factor Xa activity/mL.

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<table>
<tr><th>Claim</th><th>ProTime Microcoagulation System (K010599)
As Indicated in the ProTime Device Insert</th><th>PT•S Test Strips For Use With CoaguChek S System</th></tr>
<tr><td>Precision with controls</td><td>Precision testing was conducted with two levels of standard control plasma substrate preparations.

Standard ProTime cuvette:

<table>
<tr><th></th><th></th><th>N</th><th>mean</th><th>SD</th></tr>
<tr><td>Level I</td><td>within day</td><td>17</td><td>0.9</td><td>0.06</td></tr>
<tr><td></td><td>day to day</td><td>4/day</td><td>1.0</td><td>0.08</td></tr>
<tr><td>Level III</td><td>within day</td><td>19</td><td>3.2</td><td>0.19</td></tr>
<tr><td></td><td>day to day</td><td>4/day</td><td>3.2</td><td>0.12</td></tr>
</table>
ProTime 3 cuvette:

<table>
<tr><th></th><th></th><th>N</th><th>mean</th><th>SD</th></tr>
<tr><td>Level I</td><td>within day</td><td>18</td><td>0.9</td><td>0.07</td></tr>
<tr><td></td><td>day to day</td><td>4/day</td><td>0.9</td><td>0.12</td></tr>
<tr><td>Level III</td><td>within day</td><td>20</td><td>4.0</td><td>0.19</td></tr>
<tr><td></td><td>day to day</td><td>4/day</td><td>4.2</td><td>0.22</td></tr>
</table></td><td>The monitor-to-monitor, lot-to-lot and strip-to-strip variability was assessed during internal studies which used two levels of liquid controls, with three test strip lots across nine CoaguChek S monitors. The following data was obtained:

<table>
<tr><th>Level 1</th><th>Mean INR 1.2</th><th></th></tr>
<tr><th></th><th>SD</th><th>%CV</th></tr>
<tr><td>Lot to Lot</td><td>0.03</td><td>2.49</td></tr>
<tr><td>Monitor to monitor</td><td>0.01</td><td>0.61</td></tr>
<tr><td>Strip to strip</td><td>0.05</td><td>3.79</td></tr>
<tr><td>Total</td><td>0.06</td><td>4.57</td></tr>
</table>
<table>
<tr><th>Level 2</th><th>Mean INR 3.0</th><th></th></tr>
<tr><th></th><th>SD</th><th>%CV</th></tr>
<tr><td>Lot to Lot</td><td>0.07</td><td>2.35</td></tr>
<tr><td>Monitor to monitor</td><td>0.03</td><td>1.17</td></tr>
<tr><td>Strip to strip</td><td>0.15</td><td>5.13</td></tr>
<tr><td>Total</td><td>0.17</td><td>5.76</td></tr>
</table></td></tr>
<tr><td>Precision with blood</td><td>Not Indicated in the ProTime Insert.</td><td>Whole blood precision for venous samples was determined from sample duplicates at three external sites. Whole blood capillary data was collected from sample duplicates at two external sites.

Bland Altman plots for both capillary and venous blood are provided in the test strip insert.</td></tr>
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Claim	ProTime Microcoagulation System (K010599) As Indicated in the ProTime Device Insert	PT•S Test Strips For Use With CoaguChek S System
Accuracy	INR results generated by the ProTime and ProTime 3 cuvettes using venous and fingerstick whole blood samples were compared to INR values obtained using standard Laboratory Plasma PT Methods with samples collected in 3.2% sodium citrate tubes. The following accuracy data were obtained. Standard ProTime cuvette vs Lab (Plasma) Regression equation r n Fingerstick y=0.94x + 0.38 0.95 229 Venous y=0.91x + 0.44 0.94 232 ProTime 3 cuvette vs Lab (Plasma): Regression equation r n Fingerstick y=1.05x + 0.07 0.95 229 Venous y=0.97x + 0.19 0.95 219	506 venous samples were collected from 255 outpatients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample measured on an MLA 900 analyzer, using Ortho Recombiplastin. A scatterplot graph is provided in the test strip insert. The results are as follows: y = 1.049x - 0.08 Slp CI (1.028, 1.070) Int CI (-0.13, -0.03) Correlation = 0.975 294 capillary samples were collected from 147 outpatients at two external sites. Capillary blood samples were assayed on the CoaguChek S monitor with the PT•S test strips and venous plasma samples were measured on an MLA 900 analyzer with Ortho Recombiplastin. A scatterplot graph is provided in the test strip insert. The results are as follows: y = 1.048x - 0.10 Slp CI (1.017, 1.079) Int CI (-0.17, -0.02) Correlation = 0.969

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

OCT 24 2002

Re: k020831
Trade/Device Name: PT•S Test Strips and Controls for the CoaguChek™ S System
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS, JPA
Dated: July 22, 2002
Received: July 23, 2002

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020831

Device Name: PT•S Test Strips and Controls for the CoaguChek™ S System

Indications for Use:

The CoaguChek S System is intended for quantitative Prothombin Time (PT) testing for monitoring of warfarin therapy, using fresh capillary or non-anticoagulated venous whole blood by professional health care providers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020831

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)