K992492

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510(k) Summary, Continued

4) Device Description

The prothrombin time test is used to measure coagulation by activating the extrinsic pathway. The PT^N test is sensitive to deficiencies of factors II, V, VII, and X. The prothrombin time is an *in vitro* determination of the time required for a clot to form via the extrinsic pathway. The prothrombin time is useful in monitoring the prolonged coagulation response of patients undergoing coumarin therapy. Many diseases and drugs can prolong or prevent coagulation by altering the balance of clotting factors involved in coagulation.

The PT^N test is initiated by inserting a CoaguChek Pro PT^N test cartridge into the instrument. The instrument reads a code on the test cartridge to determine test identity and lot number. The test cartridge contains a sample application well, a reagent chamber, and a reaction path. After the instrument heats the test cartridge, a drop of fresh, whole blood is placed on the test cartridge sample application well. Blood is drawn into the reagent chamber by capillary action, where it mixes with the reagent to initiate coagulation. The blood sample moves along the reaction path until a clot forms. The laser optical system detects the clot by monitoring blood flow; endpoint is reached when the blood stops moving. The time from sample application to clot detection is the prothrombin time. The displayed result is equivalent to laboratory plasma prothrombin time results. Because each newly-manufactured lot is calibrated to an internal reference lot, any lot-to-lot variability between reagents is corrected electronically using information coded on the lot-specific code key.

5) Intended use

The CoaguChek Pro PT^N test is for the quantitative determination of the prothrombin time of freshly drawn whole blood, using the CoaguChek Pro System.

6) Comparison to predicate device

The Roche Diagnostics PT^N Test and controls for the CoaguChek Pro System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics PT Test and controls for the CoaguChek System.

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510(k) Summary

Similarities to predicate device

The CoaguChek Pro PT^N Test and Controls is similar to the CoaguChek PT Test and Controls in the following items:

Topic	Comment
Intended Use	Both are intended for the measurement of prothrombin time in whole blood samples.
Closed System	Both systems use instrument, reagent carriers, and controls that are provided by Roche and are intended to be used together.
Sample types	Both systems require whole blood samples, either venous or capillary.
Professional use	Both systems are indicated for use by health care professionals, not for over-the-counter or prescription self-testing.
Quality control procedure	The use of the reconstituted liquid controls, or the electronic quality control cartridge is the same for both systems.
Specimen collection and preparation instructions	These instructions are the same for both systems.
Test reagent dosing	For both systems, the test reagent is dosed outside of the monitor, so that there is no need for cleaning of the cartridge or strip guide or the monitor optics.
Calibration of results	Both systems are traceable to the WHO reference method.
Maintenance	No maintenance is required for either system.

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510(k) Summary, Continued

Differences from predicate device

The following table lists the major differences between the CoaguChek Pro PT^N Test and Controls and the predicate CoaguChek PT Test and Controls device:

Topic	CoaguChek PT	CoaguChek Pro PT^N
Operating principal	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.	Blood is drawn into the reagent chamber by capillary action, where it mixes with the reagent. The blood sample moves along the reaction path until a clot forms. The laser optical system detects the clot by monitoring blood flow.
Reagent carriers	Reagent is housed within a flexible plastic strip.	Reagent is housed within a rigid plastic cartridge.

Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek Pro PT^N test and the CoaguChek PT test.

Claim	CoaguChek PT Test (Predicate)	CoaguChek Pro PT^N Test
Mean Normal	12 seconds 1.0 INR	12 seconds 1.0 INR
Verified Assay Range	9.6 – 34.4 seconds 0.64 – 8.2 INR	10.7 – 37.8 seconds 0.8 – 9.9 INR
Factor Sensitivity	Factors II, V, VII, and X	Factors II, V, VII, and X

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Performance characteristics **(continued)**

Claim	CoaguChek PT Test (Predicate)	CoaguChek Pro PT^N Test
Verified Hematocrit Range	32% - 52%	23% - 53%
Precision with controls	**Control Mean CV** *Between-Day* Level 1 12.6 sec 3.7% Level 2 23.2 sec 4.1%	**Control Mean CV** *Between-Day* Level 1 11.6 sec 5.2% 0.9 INR 10.8% Level 2 21.6 sec 5.5% 3.2 INR 11.6%
Precision with blood	Capillary 17.2 sec 2.2% CV Venous 17.6 sec 1.9% CV	Capillary 17.7 sec 3.8% CV 2.31 INR 8.4% CV Venous 18.6 sec 3.3% CV 2.57 INR 8.2% CV
Accuracy	Venous Whole Blood: CoaguChek vs. MLA700 N=81 Y=0.859X + 1.3 R=0.985	Venous Whole Blood: CoaguChek Pro vs. MLA900C N=561 Y=0.974X + 0.12 R=0.922

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 2 1999

Ms. Luann Ochs
Regulatory Program Manager
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K992492
Trade Name: PT^{N} Test Cartridges and Controls for the CoaguChek Pro System
Regulatory Class: II
Product Code: GJS
Dated: October 7, 1999
Received: October 8, 1999

Dear Ms. Ochs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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): K992492
Device Name: PT^N Test and Controls for the CoaguChek Pro System
Indications for Use:

The CoaguChek Pro PT^N test cartridge is for the quantitative determination of the prothrombin time of freshly drawn whole blood, using the CoaguChek Pro System. It is intended for health care professional use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Marini

(Division Sign-Off)
Division of Clinical Laboratory Devices K992492
510(k) Number

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)