

SEP - 6 2000

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
(317) 845-2000

Contact Person: Jennifer Tribbett

Date Prepared: December 23, 1999

2) Device name Proprietary name: CoaguChek ® S System

Common name: prothrombin time test

Classification name: Prothrombin time test

3) Predicate device We claim substantial equivalence to the Roche Diagnostics Corporation CoaguChek System, K930454.

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4) Device Description

The CoaguChek S System is used for the quantitative determination of prothrombin time (PT) in fresh capillary or venous whole blood 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. People 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 CoaguChek Test Strip uses a modified version of this method.

The 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

The CoaguChek S System is used for the quantitative determination of prothrombin time (PT) in fresh capillary or venous whole blood by professional health care providers.

6) Comparison to predicate device

The Roche Diagnostics CoaguChek S 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 CoaguChek System (K930454).

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Similarities to predicate device

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

Topic	Comment
Intended Use	Both are intended for quantitative prothrombin time (PT) testing in fresh capillary or venous whole blood.
Principle of Operation	Both systems utilize the same “dancing particle” principle of operation. The PT test strip contains reagents and iron particles. Blood mixes with these reagents and particles on the test strip. At the same time, the monitor starts a timer. The iron particles move in response to an oscillating magnetic field. When the blood clots, the particles stop moving. The monitor stops the timer and displays the result.
Closed System	Both systems use instrument, reagent strips, and controls that are provided by Roche and are intended to be used together.
PT Test Strips and Controls	Both systems use the same PT test strips, liquid controls and electronic quality controls.
Quality control procedure	The recommended liquid and electronic quality control frequency is the same for both systems.
Specimen collection and preparation instructions	These instructions are the same for both systems.
Calibration of results	Both systems are traceable to the WHO reference method.

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Differences from predicate device

The following table lists the major differences between the CoaguChek S System and the predicate CoaguChek System.

Topic	CoaguChek System (Predicate)	CoaguChek S System
Monitor Display	Information is stated in text format. For example: "Apply Sample" is displayed to instruct the user to apply a blood sample.	Information is stated in icon format. For example: A picture of a test strip and a drop of blood is displayed to instruct the user to apply a blood sample.
Size	8.8 x 5.5 x 2.2 inches 223.5 x 139.7 x 55.9 millimeters	6.82 x 4.90 x 1.75 inches 173.2 x 124.5 x 44.5 millimeters
Weight	1.5 lbs. or 0.68 kilograms (Including Batteries)	1.0 lbs. or 0.454 kilograms (Including Batteries)
Memory	30 test results with time & date	60 test results with time & date

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Strip related performance characteristics

Since the PT test strip utilized by the new CoaguChek S system and the predicate CoaguChek system is the same, certain claims related directly to the strip are not impacted by the introduction of a new monitor. The following chart is provided to indicate those strip related claims that will remain the same regardless of the monitor type used.

Claim	CoaguChek System (Predicate)	CoaguChek S System
Factor Sensitivity	Factors II, V, VII, and X	Factors II, V, VII, and X
Hematocrit Range	32% - 52%	32% - 52%
Reportable Range	0.6 - 8.0 INR	0.6 - 8.0 INR
Reagent Stability	20 months	20 months

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Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek S System and the CoaguChek System.

Claim	CoaguChek System (Predicate)	CoaguChek S System
Precision with controls	<i>Between-Day</i> Control Mean CV Level 1 12.6 sec 3.7% CV Level 2 23.2 sec 4.1% CV	<i>Between-Day</i> Control Mean CV Level 1 14.9 sec 4.4% CV Level 2 20.6 sec 5.2% CV
Precision with blood	Capillary 17.2 sec 2.2% CV Venous 17.6 sec 1.9% CV	Capillary 19.4 sec 2.2% CV Venous 19.3 sec 2.7% CV
Accuracy	Venous Whole Blood: CoaguChek vs. MLA700 N=81 Y=0.859x + 1.3 R=0.985	Venous Whole Blood: CoaguChek S vs. MLA 700/1600 N=219 Y=0.935x + 0.004 R=0.904



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

SEP 6 2000

Re: K994349
Trade Name: CoaguChek S System
Regulatory Class: II
Product Code: JPA
Dated: June 7, 2000
Received: June 8, 2000

Dear Ms. Tribbett:

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.

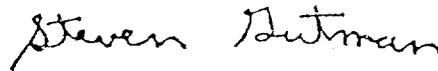
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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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 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 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): K994349

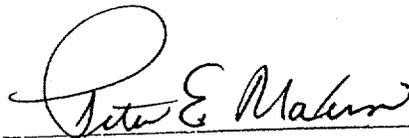
Device Name: CoaguChek S System

Indications for Use:

The CoaguChek S System is used for the quantitative determination of prothrombin time (PT) in fresh capillary or venous whole blood by professional health care providers.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Laboratory Devices

K994349

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)