4/13/99

K983892

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

Boehringer Mannheim Corporation, doing business as Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46256
(317) 845-2000

Contact Person: Luann Ochs

Date Prepared: October 30, 1998

2) Device name

Proprietary name: CoaguChek Pro System, APTT Test and Controls

Common name: Activated partial thromboplastin test

Classification name: Multipurpose system for *in vitro* coagulation studies

3) Predicate device

We claim substantial equivalence to the Biotrack monitor and APTT test cartridges and controls, K860720, K890052, K890051. The Biotrack system is also known as the Roche Diagnostics CoaguChek Plus System, APTT test and controls.

Continued on next page

4) Device Description

The APTT is used to evaluate intrinsic pathway function. The APTT is sensitive to deficiencies of factors VIII, IX, XI, and XII, prekallikrein, high molecular weight kinogen, as well as common pathway factors (II, V, X, and fibrinogen). The APTT is useful as a screening test for coagulation function, since it is sensitive to all coagulation factors except VII, platelet factor III and calcium. Additionally, the APTT is used to monitor the effectiveness of heparin therapy. Many diseases and drugs can prolong or prevent coagulation by altering the balance of clotting factors involved in coagulation.

The APTT test is initiated by inserting a CoaguChek Pro APTT 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 APTT. The displayed result is equivalent to laboratory plasma APTT 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 APTT test is for the quantitative determination of the activated partial thromboplastin time (APTT) of freshly drawn whole blood.

6) Comparison to predicate device

The Roche Diagnostics CoaguChek Pro System, APTT Test and controls, 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 Plus System, APTT Test and controls.

Continued on next page

Similarities to predicate device

The CoaguChek Pro is similar to the CoaguChek Plus in the following items:

Topic	Comment
Intended Use	Both are intended for the measurement of activated partial thromboplastin time in whole blood samples.
Closed System	Both systems use only the instrument, reagent cartridges, and controls (liquid and electronic) 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.
Operating principle	Both systems use the same instrument and reagent operating principles. Instrument operating conditions are also unchanged.
Reagent Test Cartridges	The APTT Reagent Test cartridges are exactly the same for both monitor systems. Test cartridge design, packaging (individually foil wrapped), calibration, and storage conditions are identical.

Continued on next page

Similarities to predicate device (continued)

Topic	Comment
Assay procedure	The whole blood testing procedure is unchanged.
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 cartridge dosing	For both systems, the test cartridge is dosed outside of the monitor, so that there is no need for cleaning of the cartridge guide or the monitor optics.
Maintenance	No maintenance is required for either monitor.
Limitations	The limitations of the procedure remain unchanged between the systems.
Unusual results	The instructions for action required when unusual results are obtained are the same for both systems.
Warnings and precautions	Warnings and precautions are unchanged.
Calibration of results	Test results for both methods were originally calibrated to laboratory plasma method.

Continued on next page

Differences from predicate device

The following table lists the major differences between the CoaguChek Pro and the predicate CoaguChek Plus device:

Topic	Comment
Assays	At this time, we are only submitting the APTT test for use on the CoaguChek Pro monitor. Future tests will be submitted as separate 510(k)s. The CoaguChek Plus System includes APTT as well as a PT (prothrombin time) test.
Instrument models	The CoaguChek Plus System is available with one model of monitor. The CoaguChek Pro System will be available as a base model, a direct replacement for the Plus monitor, and a DM model. The DM model includes options for use in professional settings where data reporting features are required.
Monitor displayed self-diagnostic messages.	While both monitors provide self-diagnostic messages, the CoaguChek Plus has 22 such messages, while the CoaguChek Pro has 16 self-test messages and 29 other diagnostic messages. Please refer to the appropriate operator's manuals for the listings of the messages.

Continued on next page

Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek Pro APTT test and the CoaguChek Plus APTT test. Data to support the claims for the CoaguChek Pro is included in this 510(k), in section IV.

Claim	CoaguChek Plus APTT Test (Predicate)	CoaguChek Pro APTT Test
Mean Normal	31 seconds	31 seconds
Verified Assay Range	18 – 150 seconds	18 – 150 seconds
Displayed Assay Range	18 – 150 seconds	18 – 150 seconds
Factor Sensitivity	Factors VIII, IX, XI, XII, prekallikrein, and kininogen.	Factors VIII, IX, XI, XII, prekallikrein, and kininogen.
Verified Hematocrit Range	25.5% - 53%	26.5% - 53%
Precison with controls	**Control Mean CV** *Within-Day* Level 1 55.5 sec 4.7% Level 2 116.1 sec 4.5% *Between-Day* Level 1 56.2 sec 5.8% Level 2 116.8 sec 3.8%	**Control Mean CV** *Overall* Level 1 44.2 sec 5.3% Level 2 83.4 sec 4.7%
Accuracy	Center A, n = 73 y = 1.24 x – 9.9, r = 0.78 Center B, n=71 y = 1.54 x – 22.5, r = 0.87 Center C, n=59 y = 1.51 x – 12.5, r = 0.85	Site 1, n = 55 y = 0.792 x + 8.5, r = 0.89 Site 2, n = 54 y = 1.134 x – 0.8, r = 0.93 Site 3, n = 45 y = 1.055 x + 1.1, r = 0.83

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

Ms. Luann Ochs
Regulatory Program Manager
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46256

Re: K983892
Trade Name: CoaguChek Pro System, APTT Test and Controls
Regulatory Class: II
Product Code: JPA
Dated: February 5, 1999
Received: February 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): K983892

Device Name: CoaguChek Pro System, APTT Test and Controls

Indications for Use:

The CoaguChek Pro APTT test is for the quantitative determination of the activated partical thromboplastin time (APTT) of freshly drawn whole blood. 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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983892

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

(Optional Format 1-2-96)