K992851

JAN 14 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: Luann Ochs

Date Prepared: August 23, 1999

2) Device name

Proprietary name: ACT Test and Controls for the CoaguChek Pro System

Common name: activated clotting time test

Classification name: activated whole blood clotting time test

3) Predicate device

We claim substantial equivalence to the International Technidyne Corporation ACT Test and controls for the Hemochron Whole Blood Coagulation System, K832189, K913861, K960749.

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4) Device Description

The activated clotting time test is used to measure coagulation by activating the clotting pathway. The ACT test monitors the effectiveness of heparin during several types of medical procedures. Many procedures such as Percutaneous Transluminal Coronary Angioplasty (PTCA), cardiac catheterization, hemodialysis, and Extracorporeal Membrane Oxygenation (ECMO) require the administration of low to moderate heparin doses. Sensitivity to heparin can vary significantly from patient to patient, and lack of adequate control of the heparin dose can lead to either bleeding or thrombosis.

The ACT test is initiated by inserting a CoaguChek Pro ACT 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 activated clotting time. The displayed result is equivalent to the ACT result obtained from a commercially available system. 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 ACT test is for the quantitative determination of the activated clotting time of freshly drawn whole blood, using the CoaguChek Pro System.

6) Comparison to predicate device

The Roche Diagnostics ACT 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 ACT Test and controls for the Hemochron Whole Blood Coagulation System.

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Similarities to predicate device

The CoaguChek Pro ACT Test and Controls is similar to the Hemochron ACT test and controls in the following items:

Topic	Comment
Intended Use	Both are intended for the measurement of activated clotting time in whole blood samples.
Closed System	Both systems use instrument, reagent carriers, and controls that are intended to be used together.
Sample types	Both systems require nonanticoagulated whole blood samples, either venous or arterial.
Professional use	Both systems are indicated for use by health care professionals at the point of care, not for over-the-counter or prescription self-testing.

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Differences from predicate device

The following table lists the major differences between the CoaguChek Pro ACT Test and Controls and the predicate Hemochron ACT Test and Controls device:

Topic	Hemochron ACT	CoaguChek Pro ACT
Operating principal	Dislocation of a precision aligned magnetic rod by fibrin fibers in the forming clot.	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.
Detection system	Clot formation detected by a magnetic sensor	A laser optical system detects the clot by monitoring blood flow.
Reagent carriers	Test tube containing an activator	Rigid plastic cartridge containing the reagents in a reagent well
Sample volume	2 mL	45 µL drop of blood
ACT based on	Intrinsic pathway	Extrinsic pathway
Activator	Kaolin, celite, or glass	Tissue factor + sulfatide
Initiation of ACT	Surface activation of Factor XI via Factor XIIa	Tissue factor / Factor VIIa complex
Sample/reagent mixing	Mixed manually by agitating the test tube for 10 seconds	Automatic mixing while blood is traversing the reagent well
Heparin range	Every level of heparin anticoagulation, from prophylaxis to intensive	0 – 3 U/mL
Maximal test time	1,500 seconds	500 seconds
Sensitive to aprotinin	Yes (Celite ACT only)	No

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Performance characteristics

The following chart shows a comparison of performance characteristic claims for the CoaguChek Pro ACT test and the Hemochron ACT test.

Claim	Hemochron ACT Test (Predicate)	CoaguChek Pro ACT Test
Mean Normal	132 seconds (Celite, healthy participants)	112 seconds 1.0 INR
Verified Hematocrit Range	Not in product labeling	27 – 54%
Precision with liquid controls	Not in product labeling, our studies gave: **Control Mean CV** *Between-Day* Level 1 125.45 sec 12.36% Level 2 261.08 sec 6.15%	**Control Mean CV** *Between-Day* Level 1 115.06 sec 5.79% Level 2 401.02 sec 10.34%
Precision with blood	Not in product labeling	Using arterial whole blood, duplicate results gave CVs of 6% or better.
Accuracy	Not in product labeling	Arterial Whole Blood: CoaguChek Pro vs. Hemochron: N=539 Y=0.953X + 5.3 R=0.883

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 4 2000

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

Re: K992851
Trade Name: ACT Test and Controls for the CoaguChek® Pro System
Regulatory Class: II
Product Code: JBP
Dated: December 2, 1999
Received: December 3, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K992851

Device Name: ACT Test and Controls for the CoaguChek Pro System

Indications for Use:

The CoaguChek Pro ACT test cartridge is for the quantitative determination of the activated clotting 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. Madan

(Division Sign-Off)
Division of Clinical Laboratory Devices K992851
510(k) Number

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

(Optional Format 1-2-96)