K063823

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

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

JAN 2 9 2007

Contact person: Theresa Ambrose Bush

Date prepared: December 13, 2006

Device Name

Proprietary name: CoaguChek XS PT Controls

Common name: CoaguChek XS PT Controls

Classification name: System, Multipurpose for in vitro coagulation studies

Establishment registration

The establishment registration number for Roche Diagnostics Mannheim is 961026.

Device Description

The control consists of lyophilized non-human plasma with varying levels of coagulation factors, which is reconstituted for use with diluent from a plastic bulb pipette.

Intended Use

CoaguChek XS PT Controls are intended for system checks and quality control of Prothrombin Time Testing with the CoaguChek XS monitor and CoaguChek XS PT test strips.

Substantial equivalence: Predicate Device

CoaguChek XS PT Controls is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed CoaguChek PT S System Controls cleared in the PT S Test Strips and Controls for the CoaguChek S System (K 020863 1).

Comparison table

The below tables compare CoaguChek XS PT Controls with the predicate device, CoaguChek PT S System Controls (K0208631).

Characteristic	CoaguChek XS PTControls	Predicate Device CoaguChek PT S System Controls (K0208631)

Intended Use	CoaguChek XS PT Controls are intended for system checks and quality control of Prothrombin Time Testing with the CoaguChek XS monitor and CoaguChek XS PT test strips.	for quality control testing using CoaguChek PT S Test ts with the CoaguChek S System by professional health care providers
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • Stable for 30 minutes	Unopened: • Store at 2-8°C. Do not freeze. • When stored at room temperature, controls are stable for 90 days or until expiration date, whichever comes first, when stored at room temperature (below 32°C). Reconstituted • Stable for 30 minutes
Matrix	Same	Lyophilized non-human plasma (with varied levels of coagulation factors) with aqueous diluent, stabilizers, and preservative.
Levels	Same	Two levels: Level 1 normal Level 2 abnormal
Handling	Same	Lyophilized plasma that is reconstituted with diluent from a plastic bulb pipette, mixed by swirling, set aside while meter is activated, and used within 30 minutes of reconsititution.
Precision	Level 1: overall CV 1.1% Level 2: overall CV 2.1 %	Level 1: overall CV 4.80 % Level 2: overall CV 5.46 %

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

ROCHE Diagnostics Corp.
C/O Theresa Ambrose Bush
9115 Hague Road
P.O. Box 50416
Indianapolis, Indiana 46250

JAN 2 9 2007

Re: k063823
Trade/Device Name: CoaguChek® XS PT Controls
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GGN
Dated: December 22, 2006
Received: December 26, 2006

Dear Ms. Bush:
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 Section 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), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use

510(k) Number (if known): K063823

Device Name: **CoaguChek XS PT Controls**

Indications For Use:

CoaguChek XS PT Controls are intended for system checks and quality control of Prothrombin Time Testing with the CoaguChek XS monitor and CoaguChek XS PT test strips.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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