K070585

510(k) Summary

MAY 25 2007

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.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Scott Thiel
Date Prepared: February 27, 2007

2) Device name

Proprietary name: ACCU-CHEK Performa System
Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

ACCU-CHEK Aviva System

4) Device Description

The ACCU-CHEK Performa is a blood glucose testing product and based on the ACCU-CHEK Aviva System. The ACCU-CHEK Performa system maintains performance characteristics with ACCU-CHEK Aviva.

The ACCU-CHEK Performa system is comprised of:

- The ACCU-CHEK Performa blood glucose monitor
- The ACCU-CHEK Performa blood glucose test strip
- The ACCU-CHEK Performa Control Solutions

The test principle is:
Blood from the test site works with the chemicals in the test strip to make a small electric current in the test strip. The meter reads the current and gives a blood glucose result.

Continued on next page

510(k) Summary, Continued

5) Intended use	The ACCU-CHEK Performa system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf. Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood; home use is limited to capillary whole blood testing.
6) Substantial equivalence	The Roche Diagnostics ACCU-CHEK Performa System is substantially equivalent to the current legally marketed ACCU-CHEK Aviva System.
7) Data demonstrating substantial equivalence	Performance testing on the ACCU-CHEK Performa System demonstrated that the device meets the performance requirements for its intended use. All predetermined acceptance criteria were satisfied. The data demonstrates that the ACCU-CHEK Performa is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 2007

Mr. Scott Thiel, MBA, MT(ASCP)
Regulatory Affairs Program Manager
Regulatory Affairs Diabetes Care
Indianapolis Office
Roche Diagnostic Corp.
9115 Hague Rd.
Indianapolis, IN 46256

Re: k070585
Trade/Device Name: ACCU-CHEK® Performa System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: February 27, 2007
Received: March 1, 2007

Dear Mr. Thiel:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. 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 at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

k070585
Attachment 3

Indications for Use

510(k) Number (if known): K070585

Device Name: ACCU-CHEK® Performa System

Indications For Use:

The ACCU-CHEK® Performa system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood; home use is limited to capillary whole blood testing.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use ___XX___ (21 CFR 801 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

510(k) K070585