K043474

APR 2 7 2005

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
9115 Hague Road
Indianapolis, IN 46250
(317)845-2000

Contact Person: Scott Thiel

Date Prepared: December 15, 2004

2) Device name

Proprietary name: ACCU-CHEK® Aviva System

Common name: Whole blood glucose test system

Classification name: 75, LFR, Glucose dehydrogenase, glucose

3) Predicate device

We claim substantial equivalence to the ACCU-CHEK Advantage system, K010362 and K032552.

4) Device description

The ACCU-CHEK Aviva system utilizes reagent test strips stored within a desiccated vial. A test strip is removed from the vial and inserted into the meter. Upon insertion, the meter is activated. Blood is applied to the end of the test strip, and a glucose result is reported.

The test principle is:

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

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5) Intended Use

The ACCU-CHEK® Aviva system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring blood glucose in the home or health care facility. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

6) Comparison to predicate device

The Roche Diagnostics ACCU-CHEK Aviva system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ACCU-CHEK Advantage system.

7) Similarities to predicate device

The ACCU-CHEK Aviva system is similar to the ACCU-CHEK Advantage system in the following ways:

Topic	Comment
Intended Use	Both systems are intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
Closed system	Each systems' test strips and controls are designed to be used only with that system.
Sample types	Both systems utilize whole blood samples (capillary or venous).
Home and Professional use	Both systems are intended to be used by persons in their home, or by health care professionals in health care facilities.
Test strip storage conditions	Store at room temperature, less than 90°F. Do not freeze.

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7) Similarities to predicate device (continued)

Topic	Comment
Quality control procedure	Quality controls are tested when the cap is left off the vial of test strips, when a new vial is opened, if the meter is dropped, if the result does not agree with the way the user feels, whenever the user wishes to check to performance of the system.
Reportable range	10 – 600 mg/dL
Warnings and precautions	Both systems are for *in vitro* diagnostic use only.
Monitor coding process	Both systems use a code key, included in the test strip vial, inserted into the meter.
Test strip packaging	Both systems provide test strips in a desiccated vial.

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8) Differences from predicate device

The ACCU-CHEK Aviva system and the ACCU-CHEK Advantage system differ in the following ways:

Topic	ACCU-CHEK Aviva	ACCU-CHEK Advantage
Identification of control solution results	Automatically distinguishes control solutions from whole blood samples.	User must identify (flag) the control solution result manually.
Test sample volume	0.6 uL	4.0 uL
Test time	5 seconds	26 seconds (Comfort Curve test strips)
Expiration	In addition to information included in labeling, the code key contains expiration date of associated test strips. System informs user when code key has expired.	No notification of expiration beyond that included in labeling.
Test strip technology	The system utilizes both AC/DC electrical impedance information.	The system utilizes electrical biamperometry information.

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8) Differences from predicate device (continued)

Topic	ACCU-CHEK Aviva	ACCU-CHEK Advantage
Labeling instructions regarding expected results	The normal fasting blood glucose range for an adult without diabetes is 74 – 106 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.	The normal fasting adult blood glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for their individual patients.

Benefits

ACCU-CHEK Aviva's new test strip technology is convenient and easy-to-use. Its look, feel, and handling are similar and familiar to conventional reagent test strip users.

ACCU-CHEK Aviva's new test strip technology also allows for the addition of several new test strip fail-safes:

- The ACCU-CHEK Aviva system performs more than 150 checks on the integrity of each test strip prior to use. Strips that have been exposed to excessive heat or humidity are not used to generate test results.
- The ACCU-CHEK Aviva system automatically compensates for some variation in temperature and hematocrit through the AC electrical information channel.
- The ACCU-CHEK Aviva system automatically locks out the user after the test strip expiration date has been exceeded.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 27 2005

Mr. Scott Thiel
Regulatory Affairs Program Principal
Roche Diagnostics Corp.
9115 Hague Rd
Indianapolis, IN 46260

Re: k043474
Trade/Device Name: ACCU-CHEK® Aviva System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: March 28, 2005
Received: March 29, 2005

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)276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, 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

Indications for Use

510(k) Number: K043474

Device Name: ACCU-CHEK® Aviva System

Indications For Use:

The ACCU-CHEK® Aviva system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring blood glucose in the home or health care facility. The device is intended for professional use and over-the-counter sale. Professionals may use the test strip to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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

510(k) K043474