K133862

Roche

510(k) Summary

APR 2 9 2014

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) 521-7593
Contact Person: Khone Saysana
Date Prepared: December 17, 2013

2) Device name

Proprietary name:
ACCU-CHEK® Aviva Plus Blood Glucose Monitoring System
Meter: ACCU-CHEK Aviva Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase

3) Predicate device

ACCU-CHEK Aviva Plus System (K101299)

Continued on next page

510(k) Summary, Continued

4) Device Description

The modified ACCU-CHEK Aviva meter used in conjunction with the ACCU-CHEK® Aviva Plus test strips. The new ACCU-CHEK Aviva meter no longer uses a code key.

5) Intended use

The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

The single-patient use ACCU-CHEK Aviva Blood Glucose Monitoring System will consist of:

Meter: ACCU-CHEK Aviva Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

6) Substantial equivalence

The modified ACCU-CHEK Aviva meter is substantially equivalent to the ACCU-CHEK Aviva Plus System (K101299).

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Aviva System demonstrated that the device meets the performance requirements for its intended use. The data demonstrates that the test strip is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – W066-G609
Silver Spring, MD 20993-0002

ROCHE DIAGNOSTICS CORPORATION
KHONE SAYSANA
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

April 29, 2014

Re: K133862
Trade/Device Name: ACCU-CHEK Aviva Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: March 28, 2014
Received: March 31, 2014

Dear Khone Saysana:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133862

Device Name
ACCU-CHEK Aviva Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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