Roche

K131029

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.
Indianapolis, IN 46250
(317) 521-2110
Contact Person: Khone Saysana
Date Prepared: April 10, 2013

AUG 0 9 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

Proprietary name: ACCU-CHEK® Aviva Combo System
Common Name: Insulin infusion pump, glucose test system, and accessories
Classification name:

- Pump, infusion, insulin (21 CFR 880.5725); Class II; Product Code: LZG
- Glucose test system (21 CFR 862.1345); Class II; Product Code: NBW
- Drug dosing calculator (21 CFR 868.1890); Class II; Product Code: NDC

3) Predicate device

ACCU-CHEK Aviva Plus System (K101299)
ACCU-CHEK Aviva Combo System (K111353)

4) Device Description

The modified Black Code Key used in conjunction with the ACCU-CHEK® Aviva meter and the ACCU-CHEK® Aviva Combo meter.

The Black Code Key contains a universal code and can be used on all released ACCU-CHEK Aviva Plus test strip lots.

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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

5) Intended use continued

The ACCU-CHEK Combo System is indicated for the treatment of insulin requiring diabetes and for the quantitative measurement of glucose in fresh capillary whole blood from the finger.

The ACCU-CHEK Spirit Combo Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin as prescribed by a physician. The ACCU-CHEK 360° Insulin Pump Configuration software facilitates the monitoring and programming of the pump settings.

The ACCU-CHEK Aviva Combo blood glucose system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. The ACCU-CHEK Aviva Combo blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Combo blood glucose monitoring system.

The ACCU-CHEK Aviva Plus test strips are for use with the ACCU-CHEK Aviva Combo blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The ACCU-CHEK Aviva Combo meter can also be used to interface with, and remotely control the ACCU-CHEK Spirit Combo insulin infusion pumps via radio frequency communication. The ACCU-CHEK Aviva Combo meter is also indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data.

For in vitro diagnostic use
The ACCU-CHEK Aviva Combo system is intended for single patient use and should not be shared.

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6) Substantial equivalence

The modified ACCU-CHEK Aviva Plus System with Black Code Key is substantially equivalent to the ACCU-CHEK Aviva Plus System (K101299).

The modified ACCU-CHEK Aviva Combo System with black code key is substantially equivalent to the ACCU-CHEK Aviva Combo System (K111353).

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Aviva Plus 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.

Performance testing on the ACCU-CHEK Aviva Combo 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 – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Roche Diagnostics Corporation
c/o Khone Saysana
9115 Hague Rd..
INDIANAPOLIS IN 46250

Re: K131029
Trade/Device Name: ACCU-CHEK® Aviva Combo System;
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, LFR, LZG, NDC
Dated: July 8, 2013
Received: July 10, 2013

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -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

Indications for Use Form

510(k) Number: K131029
Device Name: ACCU-CHEK Aviva Plus Test System

Indications for 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.

Prescription Use ____ AND Over-The-Counter Use __XX__
(Part 21 CFR 801 Subpart D) (Part 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 Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k): K131029

Indications for Use Form

510(k) Number: K131029
Device Name: ACCU-CHEK Aviva Combo System

Indications for Use:
The ACCU-CHEK Combo System is indicated for the treatment of insulin requiring diabetes and for the quantitative measurement of glucose in fresh capillary whole blood from the finger.

The ACCU-CHEK Spirit Combo Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin as prescribed by a physician. The ACCU-CHEK 360° Insulin Pump Configuration software facilitates the monitoring and programming of the pump settings.

The ACCU-CHEK Aviva Combo blood glucose system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. The ACCU-CHEK Aviva Combo blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Combo blood glucose monitoring system.

The ACCU-CHEK Aviva Plus test strips are for use with the ACCU-CHEK Aviva Combo blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The ACCU-CHEK Aviva Combo meter can also be used to interface with, and remotely control the ACCU-CHEK Spirit Combo insulin infusion pumps via radio frequency communication. The ACCU-CHEK Aviva Combo meter is also indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data.

For in vitro diagnostic use
The ACCU-CHEK Aviva Combo system is intended for single patient use and should not be shared.

Prescription Use __XX___ AND Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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