K113137

JAN - 6 2012

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) 521-7593
Contact Person: Khone Saysana
Date Prepared: October 18, 2011

2) Device name

Proprietary name:

ACCU-CHEK® Nano SmartView Blood Glucose Monitoring System
Meter: ACCU-CHEK® Nano Meter
Test Strip: ACCU-CHEK® SmartView Test Strip
Controls: ACCU-CHEK® SmartView 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)

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4) Device Description

The ACCU-CHEK® Nano meter was developed to utilize the ACCU-CHEK® Aviva Plus test system's technology and performance characteristics. The ACCU-CHEK® Nano meter designers took the measurement components of the ACCU-CHEK® Aviva Plus system, slightly changed the firmware and hardware supporting the new user interface and housing and embedded/programmed the strip lot code information within the meter so a physical code key or code key port are no longer used.

The ACCU-CHEK® SmartView test strip is a No Code Freedom 2 Chemistry test strip which shares the same scientific technology as the predicate device, the ACCU-CHEK® Aviva Plus test strips. The instrument's measurement method is not modified as a part of this test strip modification project.

When an ACCU-CHEK® SmartView test strip is inserted into the ACCU-CHEK® Nano meter, a small alternating current (AC) is applied until the application of blood causes a spike in the conductivity to be observed at the measurement and sample-sufficiency electrodes – both are used to assure an adequate sample has been applied.

The instrument then applies a series of AC voltages at four frequencies and reads the AC responses. These carry information about the sample type and environmental temperature; they also allow the system to perform various internal quality checks.

After the AC measures are completed, a small (DC) voltage is applied and current is observed which is proportionate to the glucose. The AC and DC information are then combined to provide a hematocrit and temperature compensated glucose result.

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5) Intended use

The ACCU-CHEK® Nano SmartView 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 or palm. The ACCU-CHEK® Nano SmartView Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK® Nano SmartView 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® Nano SmartView 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® SmartView Test Strips are for use with the ACCU-CHEK® Nano Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm.

The single-patient use ACCU-CHEK® Nano SmartView Blood Glucose Monitoring System will consist of:

Meter: ACCU-CHEK® Nano Meter
Test Strip: ACCU-CHEK® SmartView Test Strip
Controls: ACCU-CHEK® SmartView Control Solutions

6) Substantial equivalence

The modified ACCU-CHEK® Nano SmartView Blood Glucose Monitoring System is substantially equivalent to the ACCU-CHEK® Aviva Plus System (K101299).

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK® Nano SmartView Blood Glucose Monitoring 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

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics
c/o Khonesavanh Saysana
9115 Hague Road
Indianapolis, Indiana 46250-0416

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Re: k113137
Trade Name: Roche ACCU-CHEK Nano SmartView
Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: December 7, 2011
Received: December 8, 2011

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

K 113137

Device Name: ACCU-CHEK Nano SmartView Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND

Over-The-Counter Use __XX___ (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 Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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