K111353

510(k) Summary of Safety and Effectiveness

JUL 17 2012

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.

Submitted By

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USA Contact Person:
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Device Name

Proprietary name: ACCU-CHEK 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

Predicate Devices

ACCU-CHEK Spirit Insulin Pump - K060876
ACCU-CHEK Aviva Plus blood glucose monitoring system - K101299
ACCU-CHEK Pocket Compass Diabetes Management Software - K082595

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Device Description

The ACCU-CHEK Combo System includes:

- An ACCU-CHEK Spirit Combo insulin infusion pump and optional accessory software (ACCU-CHEK 360° Insulin Pump Configuration software), and
- An ACCU-CHEK Aviva Combo blood glucose monitor. Both devices utilize disposables that are already legally marketed.

The ACCU-CHEK Spirit Combo utilizes disposables that are already legally marketed:

- ACCU-CHEK FlexLink Plus
- ACCU-CHEK Ultraflex
- ACCU-CHEK Tender
- ACCU-CHEK Rapid-D
- ACCU-CHEK 3.15 ml Plastic Cartridge

The ACCU-CHEK Aviva Combo utilizes disposables that are already legally marketed:

- ACCU-CHEK Aviva Plus test strips
- ACCU-CHEK Aviva control solutions

The ACCU-CHEK Combo System is meant only for single-patient use; the device may not be used for screening or diagnosis of diabetes or for multiple-patient use.

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Intended 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 continuous 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 ACCUCHEK 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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Technical Characteristics

The ACCU-CHEK Spirit Combo Insulin Pump is an external, portable insulin pump designed for continuous delivery of insulin. The design allows the delivery of 0.05 to 25.0 units of U100 insulin per hour in basal rates and 0.1 up to 25.0 units of U100 insulin per meal or meal bolus. Factory settings default to 0.05 to 25.0 units of U100 insulin per hour in basal rates and 0.1 up to 25.0 units of U100 insulin per meal or meal bolus. ACCU-CHEK 360° Insulin Pump Configuration Software is needed to adjust the hourly basal rates in the basal rate profiles that are set to zero by the factory.

The physical method used to accomplish the pumping mechanism action is a state-of-the-art syringe mechanism.

This mechanism consists of:

- Brushless DC motor to drive the piston rod
- Telescoping piston rod connected with a thread to the cartridge plunger (plunger retention) to prevent free flow and siphoning
- Force sensor to detect occlusions in the fluid path

The ACCU-CHEK Spirit Combo Insulin pump utilizes a single AA alkaline or lithium battery, or rechargeable NiMH accumulator.

The ACCU-CHEK Spirit Combo Insulin Pump accuracy has been verified for the following delivery rates and operational conditions.

Area	Description
Delivery Rates: 1.0 I.U./h	Accuracy ± 5%
0.05 I.U./h	Accuracy ± 30%
Occlusion bolus volume: U100	Maximum Occlusion Volume with a feed rate of 1.0 IU/h" • 1.5 IU
Occlusion bolus delay time: U100	• 2 h with 1.0 IU/h • 24 h with 0.05 IU/h

The ACCU-CHEK Aviva Combo meter was developed to utilize the ACCUCHEK Aviva Plus test system's technology and performance characteristics. These test strips are calibrated to deliver plasmalike results. Blood from your fingertip reacts with the chemicals in the test strip to create a harmless electrical current in the test strip. The meter reads the current and gives you the blood glucose result. The ACCU-CHEK Aviva Combo meter and ACCU-CHEK Aviva Plus test strip are designed to be simple and easy to use. It provides accurate blood glucose test results in 5 second while requiring a very small (0.6 µ) sample.

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Performance Summary	Laboratory and Human Factors studies demonstrate that the ACCU-CHEK® Combo System performed in an equivalent manner to the predicate devices and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Roche Diagnostics
C/O Mr. Scott Thiel
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JUL 17 2012

Re: K111353
Trade/Device Name: ACCU-CHEK® Combo System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, NBW & NDC
Dated: July 9, 2012
Received: July 10, 2012

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. 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.

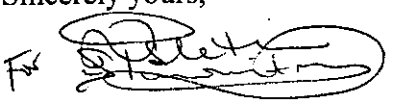
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ACCU-CHEK® Combo System

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RTC 7/16/11

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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