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

March 16, 2015

Roche Diagnostics Corporation
Ms. Chunhong Tao
Regulatory Affairs Specialist
9115 Hague Road
Indianapolis, IN 46250

Re: K141929
Trade/Device Name: ACCU-CHEK Connect Diabetes Management App
Regulation Number: 21 CFR 868.1890
Regulation Name: Drug Dosing Calculator
Regulatory Class: II
Product Code: NDC, LZG, LFR, JQP
Dated: February 9, 2015
Received: February 12, 2015

Dear Ms. Tao:

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 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,

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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)*
K141929

Device Name
ACCU-CHEK Connect Diabetes Management App

Indications for Use *(Describe)*
The ACCU-CHEK Connect Diabetes Management App is indicated as an aid in the treatment of diabetes. The software provides for electronic download of blood glucose meters, manual data entry, storage, display, transfer, and self-managing of blood glucose and other related health indicators which can be shown in report and graphical format.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K141929

Device Name
ACCU-CHEK Connect Diabetes Management App

Indications for Use *(Describe)*
The ACCU-CHEK Bolus Advisor, as a component of the ACCU-CHEK Connect Diabetes Management App, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data. Before its use, a physician or healthcare professional must activate the bolus calculator and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software.

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)

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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

Primary contact:

Mike Flis
Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2110

Secondary contact:

Chunhong (Emma) Tao
Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7227

Date Prepared: January 27, 2015

2) Device name

Proprietary Name: ACCU-CHEK Connect Diabetes Management App
Common Name: diabetes management software

Primary
Classification Name: drug dosing calculator
Classification Regulation: 21 C.F.R. § 868.1890; Class II
Product Code: NDC

Secondary
Classification Name: calculator/data processing module for clinical use
Classification Regulations: 21 C.F.R. § 880.5725, 862.1345, 862.2100; Class II
Product Code: LZG, LFR, JQP

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3) Predicate device

ACCU-CHEK Aviva Combo meter, cleared as a component of the ACCU-CHEK Combo System in #k111353.

The ACCU-CHEK Combo System consists of three (3) main components:

- ACCU-CHEK Aviva Combo blood glucose meter
- ACCU-CHEK Spirit Combo insulin pump
- ACCU-CHEK 360° Insulin Pump Configuration Software

The ACCU-CHEK Aviva Combo meter serves as a hub for the ACCU-CHEK Combo System. The monitor has three main functions:

- Blood glucose monitor
- Remote control of ACCU-CHEK Spirit Combo insulin pump
- Calculation of insulin bolus

The ACCU-CHEK Aviva Combo blood glucose meter is intended for the quantitative measurement of blood glucose. The ACCU-CHEK Aviva Combo meter 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 meter can 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.

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4) Device Description

The ACCU-CHEK Connect Diabetes Management App is designed to facilitate efficient collecting, transmitting, and analyzing of blood glucose results and other diabetes management data. The App helps:

- Wireless transfer of data from ACCU-CHEK Aviva Connect Blood Glucose Meter.
- Assist in general diabetes management through logging of contextual data.
- ACCU-CHEK Bolus Advisor support of mealtime insulin dosing calculations.
- Perform structured testing.
- Wireless transfer of data from mobile devices to ACCU-CHEK Connect Online Diabetes Management System and optionally share this data with healthcare provider (HCP) or caregiver.

The insulin bolus calculations provided by the app are meant for patients undergoing multiple daily injection therapy. Bolus calculators, such as the ACCU-CHEK Bolus Advisor, have been demonstrated to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and under the supervision of healthcare professionals experienced in managing insulin-treated patients. Such calculators have also been shown to reduce patient fear of hypoglycemia and improve patient confidence in diabetes management.

The ACCU-CHEK Connect Diabetes Management App is not intended to serve as an accessory to an insulin pump.

Continued on next page

510(k) Summary, Continued

5) Intended use

For Over-the-Counter Use:

The ACCU-CHEK Connect Diabetes Management App is indicated as an aid in the treatment of diabetes. The software provides for electronic download of blood glucose meters, manual data entry, storage, display, transfer, and self-managing of blood glucose and other related health indicators which can be shown in report and graphical format.

For Prescription Use:

The ACCU-CHEK Bolus Advisor, as a component of the ACCU-CHEK Connect Diabetes Management App, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data. Before its use, a physician or healthcare professional must activate the bolus calculator and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software.

6) Substantial equivalence

The ACCU-CHEK Connect Diabetes Management App utilizes the processing power of a mobile phone operating system platform to transfer data from a blood glucose meter, transfer data to an online diabetes management system, facilitate structured testing data collection, assist in general diabetes management through logging of contextual data, and calculate insulin bolus in response to blood glucose, health events, and carbohydrate input. These software functions were built within the predicate device's embedded software and PC-platform software. The App moves these functions outside the glucose meter. The App is compatible with glucose meters with BLE transmitter. The insulin bolus calculator algorithm is unchanged as compared to the predicate device. The App will not interact with an insulin pump. The insulin bolus calculations provided by the App are meant for patients undergoing conventional multiple daily injection therapy.

The ACCU-CHEK Connect Diabetes Management App is substantially equivalent to the drug dosage calculator function of the ACCU-CHEK Aviva Combo meter.

Continued on next page

7) Data demonstrating substantial equivalence	All necessary performance testing was conducted on the ACCU-CHEK Connect Diabetes Management App to support a determination of substantial equivalence. The results of usability testing of representative users of the device, software testing and performance testing of the device demonstrate the device functions as intended. The non-clinical testing included software verification and algorithm validation to demonstrate the functionality of the software application and the performance of the algorithms. The Human Factors clinical study demonstrated the diabetes management app fulfilled all predefined requirements for safety risk-mitigating controls when handled by persons with diabetes mellitus or their caregivers, according to its intended use. Performance testing on the ACCU-CHEK Connect Diabetes Management App demonstrated that the device meets the performance requirements for its intended use. The data demonstrate that the device is substantially equivalent to the predicate device.

Continued on next page

8) Similarities/ Differences

The following is a listing of the key similarities and differences between the ACCU-CHEK Connect Diabetes Management App and the predicate device.

Feature /Claim	ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Combo System (#k111353)
Intended Use	The ACCU-CHEK Connect Diabetes Management App is indicated as an aid in the treatment of diabetes. The software provides for electronic download of blood glucose meters, manual data entry, storage, display, transfer, and self-managing of blood glucose and other related health indicators which can be shown in report and graphical format. The ACCU-CHEK Bolus Advisor, as a component of the ACCU-CHEK Connect Diabetes Management App, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data. Before its use, a physician or healthcare professional must activate the bolus calculator and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software.	The ACCU-CHEK Aviva Combo blood glucose meter is intended for the quantitative measurement of blood glucose. The ACCU-CHEK Aviva Combo meter 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 meter can 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.
Prescription / over-the-counter use?	Over-the-counter distribution of App, with bolus calculator function disabled until activated by physician	Prescription use due to relationship with insulin pump
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with insulin pump therapy or multiple daily insulin injection (MDI) therapy
Bolus Calculator Set-up stage	During the ACCU-CHEK Connect Diabetes Management App's bolus calculator set-up stage, the following information must be	No difference, the same information is inputted into the ACCU-CHEK Combo meter during the bolus

Feature /Claim	ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Combo System (#k111353)
	entered. Time Blocks Target Range Carb Ratio Insulin Sensitivity Health Event Percentages Meal Rise Snack Size Acting Time Offset Time	calculator set-up stage.
Bolus Calculator inputs	Once the set-up stage has been completed, the patient may begin using the ACCU-CHEK Bolus Advisor in the ACCU-CHEK Connect Diabetes Management App. Bolus recommendations can be triggered by inputting the following information prior to each meal: Measure blood glucose Enter carbohydrates Enter Health Event	No difference, the same information is inputted by the patient prior to each meal to trigger a recommendation.
Communicate with insulin pumps?	No	Yes
Software Level of Concern	Major	Major
Operating platform	Mobile based application	Built within the blood glucose meter
Connectivity to Meter	Bluetooth Low Energy (BLE)	N/A
Control or affect the blood glucose meter's measurements?	No	No
Reports, graphs, and Electronic Log Book	Yes	No
Carbohydrate Calculator	Calculate carbohydrate intake based on user-entered data	Calculate carbohydrate intake based on user-entered data

Feature /Claim	ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Combo System (#k111353)
Bolus Calculator	Yes	Yes
Bolus Calculator Security	Bolus calculator function is controlled as a prescription device; the bolus calculator must be activated by licensed healthcare provider. Access to the bolus calculator function requires licensed healthcare provider activation.	The bolus calculator software is embedded within a prescription device.
Allow manual entry?	Yes	No
Back-calculation prevents insulin stacking?	Yes	Yes