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

June 3, 2015

Roche Diabetes Care Inc.
Ms. Chunhong Tao
Regulatory Affairs Specialist
9115 Hague Road
Indianapolis, IN 46250

Re: K150910
Trade/Device Name: ACCU-CHEK Connect Diabetes Management App
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: II
Product Code: NDC, LZG, LFR, JQP
Dated: May 6, 2015
Received: May 7, 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.
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)*

K150910

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

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

510(k) Number *(if known)*

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 K150910

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 Diabetes Care Inc.
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7227
Contact Person: Chunhong (Emma) Tao

Date Prepared: April 2nd, 2015

2) Device name

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

Primary
Classification Name: predictive pulmonary-function value calculator
Classification Regulation: 21 C.F.R. § 868.1890; Class II
Product Code: NDC

Secondary
Classification Regulations: 21 C.F.R. § 880.5725, 862.1345, 862.2100; Class II
Product Code: LZG, LFR, JQP

3) Predicate device

ACCU-CHEK Connect Diabetes Management App (K141929), concurrence received on March 16, 2015.

Continued on next page

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

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. The App is compatible with glucose meters with BLE transmitter. The insulin bolus calculator algorithm is unchanged as compared to the predicate device. The modification of the ACCU-CHEK Connect Diabetes Management App to work on iOS platform does not change the App's intended use or the interface to the ACCU-CHEK Aviva Connect meter or the ACCU-CHEK Connect Online diabetes management system.

The modification of ACCU-CHEK Connect Diabetes Management App is substantially equivalent to ACCU-CHEK Connect Diabetes Management App (K141929).

Continued on next page

7) Data demonstrating substantial equivalence

Modifying the ACCU-CHEK Connect Diabetes Management App to work on iOS platform does not change the App's intended use or its place within the ACCU-CHEK Connect Diabetes Management System. The modification to the ACCU-CHEK Connect Diabetes Management App does not change the data collection, tracking, trending, or transmission functions, the bolus calculator algorithm, the bolus calculator activation prescription control process, the bolus calculator activation and patient training materials, or the bolus calculator user interface screens.

The risk assessment for the iPhone version relied heavily on the risk assessment performed for the Android OS version of the App. The project management staff assessed potential faulty conditions and monitored ACCU-CHEK Connect Diabetes Management App post launch (Android OS version) to identify any possible faulty conditions that might lead to possible hazards for the patient. A risk analysis according to the "Risk Reduction Principle" laid down in the harmonized ISO standard "14971 Medical Devices – Application of risk management to medical devices" was carried out for the ACCU-CHEK Connect App. Possible hazards and consequences were systematically identified and evaluated by using the "Failure Mode Effect and Criticality Analysis" technique. Where appropriate, adequate protection measures relating to the risk that cannot be eliminated have been implemented, as well as safety information described in the instructions for use.

Design verification bench testing on the modification of ACCU-CHEK Connect Diabetes Management App demonstrated that the device meets the performance requirements for its intended use. The data demonstrate that the new device is substantially equivalent to the predicate device.

A Human Factors expert evaluation was performed to show that the predicate design validation can be used to support iPhone version's design validation. Three types of changes were reviewed using side-by-side comparison of screenshots from the Android version and the iPhone version:

1. Changes based on the inherent differences between the iOS and Android operating systems (OS) user interface standards
2. Enhancements that were made based upon results of the Android version summative and iPhone version formative human factors study
3. Changes to Validation study tasks

All of the changes are attributed to user interface standard differences between iOS and Android operating systems or to enhancements to the user experience. No new use-related hazard was identified during the expert evaluation. This expert evaluation supports design validation of the product.

Continued on next page

8) Similarities/ Differences

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

Feature /Claim	Modified ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Connect Diabetes Management App (#k141929)
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.	Same
Prescription / over-the-counter use?	Over-the-counter distribution of App, with bolus calculator function disabled until activated by physician	Same
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Same
Accessory to Blood Glucose Meters?	ACCU-CHEK Aviva Connect blood glucose meter	Same

Feature /Claim	Modified ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Connect Diabetes Management App (#k141929)
Bolus Calculator Set-up stage	During the modified ACCU-CHEK Connect Diabetes Management App's bolus calculator set-up stage, the following information must be entered. · Time Blocks · Target Range · Carb Ratio · Insulin Sensitivity · Health Event Percentages · Meal Rise · Snack Size · Acting Time · Offset Time	Same
Bolus Calculator inputs	Once the set-up stage has been completed, the patient may begin using the ACCU-CHEK Bolus Advisor in the modified 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	Same
Communicate with insulin pumps?	No	No
Software Level of Concern	Major	Major
Connectivity to Meter	Bluetooth Low Energy (BLE)	Same
Control or affect the blood glucose meter's measurements?	No	No
Reports, graphs, and Electronic Log Book	Yes	Yes

Feature /Claim	Modified ACCU-CHEK Connect Diabetes Management App	ACCU-CHEK Connect Diabetes Management App (#k141929)
Structured Testing	Facilitate the collection of Structured Testing data	Same
Carbohydrate Calculator	Calculate carbohydrate intake based on user-entered data	Same
Bolus Calculator	Yes	Yes
Bolus Calculator Security	The patients will be instructed to request an activation code from their healthcare providers; the healthcare providers will decide whether any additional multiple daily injection therapy training should be provided to the patient prior to activating the app's bolus calculator function.	Same
Allow manual entry?	Yes	Yes
Back-calculation prevents insulin stacking?	Yes	Yes
Operating platform	iOS platform	Android platform
UI Standards	iOS standards	Android standards
Size and Spacing	iOS phones with smaller viewable screens	Android phones with larger viewable screens
Meter Pairing Code	iOS standard Bluetooth pairing code	Android standard Bluetooth pairing code