December 13, 2018

Roche Diabetes Care
Ginger Emrich
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

Re: K181131
Trade/Device Name: Accu-Chek Guide Me Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: November 12, 2018
Received: November 13, 2018

Dear Ginger Emrich:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181131

Device Name
Accu-Chek Guide Me Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Accu-Chek Guide Me Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Me meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

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:

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"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."

510(k) SUMMARY: k181131

INTRODUCTION

According to the requirements of 21 CFR 807.92, the following information is intended to introduce the Accu-Chek Guide Me Blood Glucose Monitoring System, and provide sufficient detail to support a determination of substantial equivalence for k181131.

Submission Number	k181131
Submission Type	Special 510(k)
Submitter Name	Roche Diabetes Care
Address	9115 Hague Road Indianapolis, IN 46250
Contact	Primary: Ginger Emrich Phone: (317) 521-4037 Email: ginger.emrich@roche.com Secondary: Susan Hollandbeck Phone: (317) 521-3380 Email: susan.hollandbeck@roche.com
Date Prepared	November 12, 2018
Proprietary Names	Accu-Chek Guide Me Blood Glucose Monitoring System
Common Names	Glucose test system
Classification Names / Product Codes	Blood Glucose Test System, Over the Counter (21 C.F.R. § 862.1345, Product Code NBW); Class II
Predicate Device	Accu-Chek Guide Blood Glucose Monitoring System (k160944), clearance received on August 31, 2016.

DEVICE DESCRIPTION

The Accu-Chek Guide Me Blood Glucose Monitoring System makes use of the Accu-Chek Guide Me meter, and the Accu-Chek Guide test strips. This system is a single-patient use blood glucose monitoring system intended to be used to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Me Blood Glucose Monitoring System consists of the following:

- Accu-Chek Guide Me meter
- Accu-Chek Guide test strips (previously cleared in k160944)

INTENDED USE

The Intended Use is **identical** to the predicate device with the exception of the device name. The intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).

The Accu-Chek Guide Me Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Me meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

TECHNOLOGICAL CHARACTERISTICS

The Accu-Chek Guide test strip, measurement engine, and measurement principle used with the Accu-Chek Guide Me system have not been modified. System claims and performance have not changed.

The Accu-Chek Guide Me meter reflects the following modifications of the cleared Accu-Chek Guide meter:

- Updated user interface
- Fixed segment display
- 3 button interface
- Modified meter housing - design / materials
- No strip eject, strip port light, target range indicator or beeper / reminders
- No pattern detection or meal indicator
- BLE pairing with fixed PIN (on meter backlabel); only supports one pairing at a time

Similarities to Predicate Device

The following table shows the similarities of the modified device to the predicate device.

Table 1: Similarities to Predicate Device

	Accu-Chek Guide Predicate (k160944)	Accu-Chek Guide Me Modified Device
Indications for Use	Quantitatively measure glucose in fresh capillary whole blood from the finger, palm, and upper arm as an aid in monitoring the effectiveness of glucose control	Same
Alternative Site Testing	Palm and Upper arm	Same
Enzyme	FAD-GDH	Same
Test Principle	Amperometric Detection	Same
Primary Container (Vial)	Black, flip top oval vial, holds up to 50 strips Closed vial height: 51 mm Width at widest point: 18.3 mm Width at narrowest point: 15.3 mm	Same
Sample Volume	600 nanoliters	Same
Measurement Range	20 – 600 mg/dL	Same
Hematocrit Range	10 – 65%	Same
Operating Temperature Range	6 – 45 °C	Same
Operating Relative Humidity Range	10 – 90%	Same
Auto Control Solution Identification	Yes	Same
Connectivity	USB for PC connectivity and BLE (Bluetooth Low Energy) for wireless connectivity	Same
Maximum Altitude	10,150 feet	Same
Underdose Detection	Yes	Same
Coding	No	Same
Averages	7, 14, 30, and 90 Day Average	Same
System Integrity Fail-safe checks	Same	
Strip Handling / Dosing	Same	

Differences to Predicate Device

The following table shows the differences of the modified device to the predicate device.

Table 2: Differences to Predicate Device

	Accu-Chek Guide Predicate (k160944)	**Accu-Chek Guide Me** Modified Device
Target Range Indication	Yes	No
Pattern Detection	Yes	No
Meal Indication	Yes	No
Beeper / Reminders	Yes	No
Strip Light	Yes	No
Strip Ejector	Yes	No
BLE Pairing	BLE pairing with variable PIN (new PIN generated electronically at each pairing); able to pair with 5 devices at a time	BLE pairing with fixed PIN (on meter backlabel); only supports one pairing at a time
Screen / Display	Dot Matrix LCD Display with Backlight	Fixed Segment LCD Display without Backlight
Meter Buttons	Hard cap front button 4-way rocker design including OK/Power, back, and up/down functions	One Hard cap OK/Power button on the side 2 soft buttons for memory recall, and forwards / backwards functions
Meter Housing Materials	PET, IMD, PC, TPE, and ABS/PC	PET, IMD, PC, and Silicone Rubber

SUBSTANTIAL EQUIVALENCE

The submitted information in this premarket notification supports a substantial equivalence decision. The differences between predicate and modified devices do not impact the indications for use or fundamental scientific technology.