May 6, 2022

Roche Diabetes Care, Inc.
Kelly Brennan
Regulatory Compliance Lead
9115 Hague Road
Indianapolis, Indiana 46250-0457

Re: K203711
Trade/Device Name: IWL2020 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: January 31, 2022
Received: February 1, 2022

Dear Kelly Brennan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203711

Device Name
IWL2020 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The IWL2020 Blood Glucose Monitoring System is comprised of the IWL2020 meter and IWL2020 test strips.
The IWL2020 Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip as an aid in monitoring the effectiveness of glucose control.
The IWL2020 Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes at home.
The IWL2020 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.

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.

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K203711 - IWL2020 Blood Glucose Monitoring System 510(k) Summary

Submitter Details [21 CFR 807.92(a)(1)]

Submitter Name: Roche Diabetes Care, Inc.
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Device Name [21 CFR 807.92(a)(2)]

Device Trade Name: IWL2020 Blood Glucose Monitoring System
Common Name: Glucose test system
Classification Names: Blood Glucose Test System, Over the Counter; Glucose dehydrogenase
Regulation Number: 862.1345, Class II
Product Code: NBW

Legally Marketed Predicate Devices [21 CFR 807.92(a)(3)]

Predicate #: K160944
Predicate Trade Name: Accu-Chek Guide Blood Glucose Monitoring System
Product Code: NBW

Device Description Summary [21 CFR 807.92(a)(4)]

The IWL2020 Blood Glucose Monitoring System consists of the following components:
- IWL2020 Meter
- IWL2020 Blood Glucose Test Strips
- IWL2020 Control Solutions

The IWL2020 Blood Glucose Monitoring System is a handheld device that incorporates features to aid in self-monitoring of blood glucose. The blood glucose results are displayed on the screen and stored in the meter's memory, and may also be transmitted via Bluetooth Low Energy (BLE) wireless communication. Our blood glucose monitoring system creates a glucose result from an amperometric reaction. Capillary whole blood from the user's fingertip reacts with the chemicals in the test strip to create a harmless electrical current in the test strip. The blood glucose meter reads the current and gives a blood glucose result.

Intended Use/Indications for Use [21 CFR 807.92(a)(5)]

The IWL2020 Blood Glucose Monitoring System is comprised of the IWL2020 meter and IWL2020 test strips.
The IWL2020 Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip as an aid in monitoring the effectiveness of glucose control.
The IWL2020 Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes at home.
The IWL2020 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.

Indications for Use Comparison [21 CFR 807.92(a)(5)]

The indications for use of the candidate device are the same as the predicate with the exception that the Alternate Site Testing (AST) claim will not be made with the candidate device.

Technological Comparison [21 CFR 807.92(a)(6)]

The IWL2020 Blood Glucose Monitoring System measurement engine, measurement principle, and control solutions are the same as those used in the Accu-Chek Guide Blood Glucose Monitoring System. The candidate and predicate devices share the same technological characteristics including design, material, chemical composition, principle of operation, and energy source.
The IWL2020 Blood Glucose Monitoring System differs from the cleared Accu-Chek Guide Blood Glucose Monitoring System as follows:

- Guide Blood Glucose Monitoring System: Palm, Forearm, Upper Arm;
- IWL2020 Blood Glucose Monitoring System: No AST claim

- Guide Blood Glucose Monitoring System: Dot Matrix Display;
- IWL2020 Blood Glucose Monitoring System: Fixed Segment

- Guide Blood Glucose Monitoring System: 1 Button;
- IWL2020 Blood Glucose Monitoring System: 2 Buttons

Similarities / Differences from Candidate Device to Predicate Device

Product feature	Accu-Chek Guide Blood Glucose Monitoring System (Predicate Device)	IWL2020 Blood Glucose Monitoring System (Candidate Device)
Indications for Use	Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	Same
Alternate Site Testing	Palm, Forearm, and Upper Arm	No AST Claim
Enzyme	FAD-GDH	Same
Test Principle	Amperometric Detection	Same
Primary Container (test strip vial)	Black, flip top oval vial, holds up to 50 strips	Black flip top round vial, holds up to 50 strips
Sample Volume	600 nanoliters	Same
Sample Test Time	≤ 5 seconds	Same
Measurement Range	20-600 mg/dL	Same
Units of Measurement	mg/dL	Same
Hematocrit Range	10-65%	Same
Operating Temperature Range	4-45 ℃	Same
Operating Relative Humidity Range	10-90%	Same
Maximum Altitude	10,150 feet	Same
Underdose Detection	Yes	Same
Batteries	2 CR2032	Same
Control Solution	Aqueous, 2 Levels	Same
Display	Dot Matrix LCD	Fixed Segment LCD

Backlight	Yes	Same
Buttons	1	2
Strip Ejector	Yes	Same
Connectivity	USB for PC connectivity and BLE (Bluetooth Low Energy) for wireless connectivity	Same

Non-Clinical & Clinical Testing Summary and Conclusions [21 CFR 807.92(b)]

Design verification and validation testing was performed to ensure the IWL2020 Blood Glucose Monitoring System met design specifications and requirements. Testing is summarized below:

Within-Run Precision Evaluation

Ten replicate assays were each run on ten IWL2020 meters using three strip lots. Venous blood samples at eight concentration levels were used in the testing. The results are summarized below.

Glucose Level	Mean	Standard Deviation or % CV
1 (20 mg/dL)	16.6	1.1 mg/dL
2 (40 mg/dL)	38.3	1.2 mg/dL
3 (80 mg/dL)	82.5	1.8 mg/dL
4 (130 mg/dL)	138.7	2.1
5 (200 mg/dL)	216.7	2.3
6 (325 mg/dL)	367.0	2.7
7 (450 mg/dL)	479.7	2.6
8 (550 mg/dL)	575.1	2.6

Intermediate Precision Evaluation

Ten replicate assays were each run on ten IWL2020 meters using three strip lots. Linearity solutions at six concentration levels were used in the testing. The results are summarized below.

Glucose Level	Mean	Standard Deviation or %CV
1	27.8	1.3 mg/dL
2	44.4	1.3 mg/dL
3	113.6	2.6
4	291.9	2.3
5	495.1	2.0
6	541.4	2.2

Linearity Evaluation

Blood samples were prepared to a hematocrit range of 36-52% and were run on 36 IWL2020 meters using strips from three lots. Samples were prepared at eleven blood glucose concentration levels as shown below.

Level	Glucose Concentration Level
1	1-9 mg/dL
2	15-25 mg/dL
3	30-50 mg/dL
4	51-70 mg/dL
5	80-100 mg/dL
6	110-130 mg/dL
7	135-165 mg/dL
8	175-225 mg/dL
9	275-325 mg/dL
10	420-480 mg/dL
11	550-650 mg/dL

Linear regression analysis results are shown below.

Strip Lot	Slope	Y-Intercept	R-squared
All Lots	1.07	0.9342	0.9985

The results of the linearity study support the glucose measurement range of 20-600 mg/dL for the IWL2020 Blood Glucose Monitoring System.

Interference

Interference testing was performed and all compounds met the acceptance criteria with the exception of abnormally high concentrations (> 5 mg/dL) of ascorbic acid and xylose.
The labeling contains the following limitations:
"Abnormally high concentrations (greater than 5 mg/dL) of ascorbic acid (vitamin C) may cause inaccurate results. High-dose vitamin C therapy that would result in abnormally high concentrations is typically prescribed by your healthcare professional. If you are not sure if this applies to you, please check with your healthcare professional."
"Do not use during or soon after xylose absorption testing since xylose may cause inaccurate results. Xylose absorption testing is performed under the supervision of a doctor. Ask your doctor how long to wait after xylose testing before performing a blood glucose test."

Flex Studies

Flex studies were used to validate the insensitivity of the test system to performance variation due to factors that may contribute to erroneous results when used in home use settings rather than in laboratory or professional healthcare settings. The robustness of the system was validated through mechanical vibration and shock testing, operating conditions (temperature and humidity) testing, altitude effects testing, and stability testing. Additional sources of error that were tested included samples outside the measuring range, short sample detection, sample perturbation, intermittent sampling, and testing with used strips. In all of the tests, the system operated within its specified operating ranges even under stress conditions, and errors were correctly displayed when outside the meter's operating ranges.

Electromagnetic Interference and Electrical Safety

The system passed electrical and safety testing according to national and international standards including IEC 61010-1, IEC 60601-1-2, IEC 61010-2-101, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-6, and IEC 61000-4-8.
The system passed EMC testing to national and international standards including IEC 60601-1-2, and FCC 47 CFR 15 Part B.

Software

Based on the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005, testing and documentation for Major level of concern software was completed.

Clinical Performance

A clinical (user evaluation) study was conducted with IWL2020 Blood Glucose Monitoring System in the intended user population, i.e. lay persons who perform self-testing using capillary whole blood, in the United States. The study data were presented evaluating the system accuracy of the IWL2020 Blood Glucose Monitoring System compared to the Roche/Hitachi cobas c 501 PCA-HK reference method. Study results indicated that non-professional, inexperienced lay persons were able to obtain sufficiently accurate blood glucose readings when using the IWL2020 Blood Glucose Monitoring System compared to the comparator Roche/Hitachi cobas c 501 PCA-HK blood glucose readings obtained by trained technicians. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User Guide and the overall performance of the IWL2020 Blood Glucose Monitoring System. Users were able to achieve the following level of accuracy compared to the reference method:

(within ±20% of laboratory)	(99%) 346 of 350 results
Accurate Results (within ±15% of laboratory)	(96%) 336 of 350 results
More Accurate Results (within ±10% of laboratory)	(88%) 307 of 350 results
Most Accurate Results (within ±5% of laboratory)	(63%) 220 of 350 results

Conclusions

The results of nonclinical and clinical performance testing demonstrate that the candidate device has a substantially equivalent safety and effectiveness profile to the predicate device and should perform as intended in the specified use conditions as well as the predicate device per required standards.