June 7, 2024

Abbott Diabetes Care, Inc.
Arul Sterlin
Director Regulatory Affairs & Program Management
1360 South Loop Road
Alameda, California 94502

Re: K233861
Trade/Device Name: Libre Rio Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitor For Non-Intensive Glucose Management, Over-The-Counter
Regulatory Class: Class II
Product Code: SBH
Dated: December 5, 2023
Received: December 6, 2023

Dear Arul Sterlin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
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)*
K233861

Device Name
Libre Rio Continuous Glucose Monitoring System

Indications for Use *(Describe)*
The Libre Rio Continuous Glucose Monitoring System is an over-the-counter (OTC) integrated continuous glucose monitoring (iCGM) device indicated for non-insulin using persons age 18 and older. The System detects trends and tracks patterns and aids in the detection of euglycemia, hyperglycemia, and hypoglycemia. The System is also intended to autonomously communicate with digitally connected devices.

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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5. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: New Application

5.1 Submitter:

Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502

Contact: Arul Sterlin
Title: Director Regulatory Affairs & Program Management
Phone: (510) 219-9737

Date Prepared: June 4, 2024

5.2 Device Names and Classification:

Name of Device:	Libre Rio Continuous Glucose Monitoring System
Common Name:	Integrated continuous glucose monitor for non-intensive glucose management, over-the-counter
Regulatory Section:	21 CFR 862.1355
Classification:	Class II
Product Code(s):	SBH
Review Panel:	Clinical Chemistry

5.3 Predicate Device

Predicate Device:	FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)

5.4 Indications for Use

The Libre Rio Continuous Glucose Monitoring System is an over-the-counter (OTC) integrated continuous glucose monitoring (iCGM) device indicated for non-insulin using persons age 18 and older.

The System detects trends and tracks patterns and aids in the detection of euglycemia, hyperglycemia, and hypoglycemia. The System is also intended to autonomously communicate with digitally connected devices.

Contraindication

Diathermy: Remove all parts of your System before high-frequency electrical heat (diathermy) treatment. The effect of diathermy on the System hasn't been tested. The exposure may damage the Sensor, which could impact proper device function and cause inaccurate readings.

5.5 Device Description

The Libre Rio Continuous Glucose Monitoring System (herein referred to as the 'System') is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose measurements every minute to facilitate calculation of glucose values accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). The System is intended for over-the-counter use in a home setting.

The System consists of the following components: a Sensor which transmits via Bluetooth Low Energy (BLE), and a mobile application Libre Rio App that is downloaded to a compatible smartphone running iOS and Android operating system.

Libre Rio Sensor

- The Sensor is single use, disposable, and powered by a silver oxide battery. The Sensor is provided through a Sensor Applicator (which includes an electron beam sterilized sub-component) which is used to apply the Sensor to the back of the user's arm. The Sensor continuously measures glucose concentration in interstitial fluid and has an eight (8) hour memory capacity. The Sensor is factory calibrated, does not require fingerstick calibration, and can be worn for up to 15 days.

Libre Rio App

- When downloaded to a compatible smartphone, the Libre Rio App uses Near Field Communication (NFC) to start new Sensor and uses Bluetooth Low Energy (BLE) to receive glucose data from the Sensor. The user can view real-time glucose information, trend information, and historical information on the App. As a mobile application, the Libre Rio App allows connectivity with cloud-based applications. The App is distributed using the Apple App Store and Google Play Store and a list of compatible devices is accessible in the App via the Help feature or product website.

The Libre Rio Continuous Glucose Monitoring System is compatible with the Libre Data

Sharing API cleared under K223537. The display device of the connected Libre Rio System, which directly receives the data from the Sensor, continues to serve as a primary display device for the glucose data.

5.6 Substantial Equivalence

The similarities and differences between the subject and the predicate device are highlighted in the tables below.

Similarities		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device: Libre Rio Continuous Glucose Monitoring System**
Intended use	The System is intended to monitor interstitial fluid glucose concentrations and communicate with digitally connected devices.	Same
Device type	Integrated CGM	Same
Principle of operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Test range	40 to 400 mg/dL	Same
Clinical setting / sites of use	Home use	Same
System components	On-body sensor (User assembles Sensor Applicator and Sensor Pack prior to applying the Sensor) Compatible Receiver (App or Reader)	Same On-body sensor (User assembles Sensor Applicator and Sensor Pack prior to applying the Sensor) Compatible Receiver (App)
Location of glucose algorithm	Receiver	Same
Data displayed	Current glucose value, current glucose trend, graph with recent glucose history, user entered events	Same
Method of Sensor activation	Near Field Communication (NFC)	Same
Blood glucose meter (BGM)	While using the App, user must have access to a blood glucose monitoring system as the App does not provide one	Same
Wireless communication protocol	NFC: 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same
BLE communication range	20 feet unobstructed	Same

Similarities		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device: Libre Rio Continuous Glucose Monitoring System**
Method of communication and connectivity with cloud-based applications	Can communicate wirelessly to LibreView	Same
Sensor glucose algorithm	ADC Glucose Algorithm established for the predicate device	Same
Sensor calibration	Factory calibrated	Same
Compatible Sensor warmup time	1 hour	Same
Compatible Sensor life	Up to 15 days (automatic Sensor shut off)	Same
Anatomical Sensor wear locations	Back of the upper arm	Same
Sensor dimension	5 mm height / 30 mm diameter	Same
Sensor tail dimension	5.5 mm depth, 0.3 mm width	Same
Sensor power supply	Silver oxide battery (not replaceable or rechargeable)	Same
Glucose reading update interval	Every 1 minute	Same
Vitamin C Inteference information	Users can take up 1000 mg of ascorbic acid (Vitamin C) per day and use the Sensor readings to make treatment decisions	Same
System Alarms	Replace Sensor, Sensor Ended, App Stopped	Same
Scan-based alerts	Scan Error, Sensor Error, Replace Sensor, Sensor Ended, Check Sensor	Same
Method of data transfer to backfill data gap after signal loss	NFC – last 8 hours of historical data transfer upon user-initiated scan	Same
Glucose trend arrow	↑, > +2 mg/dL/min ↗, +1 to +2 mg/dL/min →, -1 to +1 mg/dL/min ↘, -2 to -1 mg/dL/min ↓, < -2 mg/dL/min	Same

Similarities		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device: Libre Rio Continuous Glucose Monitoring System**
Situations where fingerstick test is required to confirm sensor reading	• The user's symptoms do not match the glucose values displayed by the device. • The device does not show a glucose value • During the first 12 hours of wear during which the check blood glucose icon is displayed	Same
Compatibility with connected devices	Compatible with digitally connected devices	Same
Compatible operating systems and hardware platform	App is compatible with: • iOS operating system and Apple iPhone • Android operating system and Android-enabled phone	Same
Application Programming Interfaces (APIs)	Enables users to share their glucose data with authorized client software. Can communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method, the Libre Data Sharing API.	Same

Differences		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device: Libre Rio Continuous Glucose Monitoring System**
Indications for use	The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 2 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.	The Libre Rio Continuous Glucose Monitoring System is an over-the-counter (OTC) integrated continuous glucose monitoring (iCGM) device indicated for non-insulin using persons age 18 and older. The System detects trends and tracks patterns and aids in the detection of euglycemia, hyperglycemia, and hypoglycemia. The System is also intended to autonomously communicate with digitally connected devices.

Differences		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device: Libre Rio Continuous Glucose Monitoring System**
	The System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.	
Intended use population	Persons with diabetes age 2 and older	Non-insulin using persons age 18 and older
Device use	Prescription use	Over the counter
Contraindications against MRI/diathermy/CT	MRI, Diathermy and CT	Diathermy
Caution and warning against X-ray	Yes	No
Compatible Sensor	FreeStyle Libre 2 Sensor	Libre Rio Sensor
Primary display device	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App	Libre Rio App
Navigation	Side panel navigation	Bottom bar navigation menu
App Stopped alert	iOS only	iOS and Android
Optional alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Not Applicable
Mandatory glucose alarm	Urgent Low Glucose Alarm	Not Applicable
Method to display current glucose result and trend arrow	BLE for glucose data transfer. User-initiated scan via NFC required to display glucose data.	Bluetooth Low Energy (BLE). Data automatically transfers and displays glucose data without user-initiated scan (streaming data). A user-initiated scan can also be performed to display real-time glucose data and historical data, consistent with the predicate App.

5.7 Comparison of Technological Characteristics with the Predicate Device

Amperometric measurement of glucose concentration (via glucose oxidase chemical reaction) in the interstitial fluid is the technological principle for both the subject and predicate devices. The Sensor is held in place with an adhesive pad and incorporates a subcutaneously implanted sensor component and associated electronics. The electrochemical sensor component uses glucose oxidase enzyme to oxidize glucose and transfer electrons to an electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the subcutaneous space. The electrical current signal is converted a glucose value (in mg/dL) for display to the user on the App.

At a high-level, the subject and predicate devices are based on the following technological

elements:

- Compatibility with system-specific Sensor
- Use of NFC interface for starting new Sensors
- Use of BLE interfaces for wireless communication with the Sensor
- Use of software algorithm for conversion of the raw glucose measurements from the Sensor to calculate glucose results
- Ability to display of glucose results from Sensors after a user-initiated scan via NFC.
- Inclusion of App software interface to wirelessly communicate with cloud-based application.
- Libre Data Sharing API to communicate iCGM data with authorized client software for specific and permitted use cases in accordance with the cleared intended use environments.

The following major technological differences exist between the subject and predicate devices:

- The subject device Libre Rio App allows automatic display of glucose results from the Libre Rio Sensor without a user-initiated scan. The predicate FreeStyle Libre 2 App required a user initiated scan to display glucose results.
- The subject device Libre Rio App does not issue glucose alarms or signal loss alarm whereas the predicate device issues the below listed alarms:
    - Optional alarms – Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm
    - Mandatory glucose alarm – Urgent Low Glucose Alarm
- The subject device labeling removes the contraindications against CT scan and MRI. The Libre Rio Sensor is labeled MR conditional.
- The subject device labeling removes the caution and warning against X-ray.

5.8 Summary of Performance Testing

The following performance characteristics were evaluated to support substantial equivalence:

- Software Verification and Validation – Software verification and validation testing and evaluation was conducted in accordance with IEC 62304 and documentation was provided as recommended by FDA Guidance "*Content of Premarket Submissions for Device Software Functions*" issued June 14, 2023, and FDA Guidance "*Multiple Function Device Products: Policy and Considerations",* dated July 29, 2020. Results of executed protocols met the acceptance criteria and therefore support that the System software is acceptable for its intended use.

- Cybersecurity – ADC has provided cybersecurity risk management documentation for the System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the System accordance with FDA guidance document, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*" issued Sept 27, 2023. For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality, integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested.

- Interoperability – The subject device incorporated an approach for interoperability developed in alignment with FDA guidance "*Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices*" issued September 6, 2017.

- Human Factors – ADC conducted a risk analysis of the design and user interface in accordance with ANSI/AAMI/IEC 62366, IEC 60601-1-6 and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". The analysis and the study performed demonstrated that the changes implemented for the subject device meet the usability requirement for its intended use.

- Bench Testing – The subject device underwent additional safety and compatibility performance testing for the sensors to support removal of contraindications against computerized tomography (CT) scans, the modification of the magnetic resonance imaging (MRI) contraindication to magnetic resonance (MR) conditional, and the removal of the caution and warning against X-ray. The test results showed all functionality testing acceptance criteria was met.

The Libre Rio Sensor is identical to the predicate FreeStyle Libre 2 Sensor and no design changes were introduced to allow compatibility to the Libre Rio App. Therefore, the following supportive performance characteristics established for the predicate device (K222447) is applicable to the subject device and is not impacted.

- Biocompatiblity
- Sterility
- Shelf Life Stability
- Packaging Integrity/Shipping Integrity
- Electrical Safety and Electromagnetic Compatibility
- Mechanical Design Testing
- Clinical Performance

5.9 Conclusion

The Libre Rio Continuous Glucose Monitoring System has the same intended use and clinical application as the predicate device. There are no differences in the technologal characteristics that raise different questions of safety and effectiveness. Based on the performance testing and data provided in this pre-market notification, the subject device and predicate device have been shown to be substantially equivalent.