510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K233861

B Applicant

Abbott Diabetes Care, Inc.

C Proprietary and Established Names

Libre Rio Continuous Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SBH	Class II	21 CFR 862.1355 - Integrated Continuous Glucose Monitor For Non-Intensive Glucose Management, Over-The-Counter	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Blood glucose from interstitial fluid.

C Type of Test:

Quantitative, amperometric assay (Glucose Oxidase).

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Contraindication
Diathermy: Remove all parts of your Libre Rio Continuous Glucose Monitoring 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.

Do not use the Libre Rio Continuous Glucose Monitoring System if you are on dialysis or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the System.

Only apply the Libre Rio Continuous Glucose Monitoring System Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.

Taking more than 1000 mg of Vitamin C per day may falsely raise your Libre Rio Continuous Glucose Monitoring System readings. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

D Special Instrument Requirements:

Not Applicable.

IV Device/System Characteristics:

A Device Description:

The Libre Rio Continuous Glucose Monitoring System (herein referred to as the 'Libre Rio System' or '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. The Libre Rio 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 of the glucose data.

B Principle of Operation:

The Libre Rio Continuous Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor is held in place with an adhesive pad and incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a 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 ISF. The system converts the electrical current signal to a glucose value (in mg/dL) for display to the user on a display device.

C Instrument Description Information:

1. Instrument Name:

   Libre Rio Continuous Glucose Monitoring System

2. Specimen Identification:

   Not applicable

3. Specimen Sampling and Handling:

   Not applicable

4. Calibration:

   The sensor is factory calibrated and does not require calibration from the user/operator.

5. Quality Control:

   Not applicable

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
FreeStyle Libre 2 Flash Glucose Monitoring System

B Predicate 510(k) Number(s):
K222447

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233861	K222447
Device Trade Name	Libre Rio Continuous Glucose Monitoring System	FreeStyle Libre 2 Flash Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The System is intended to monitor interstitial fluid glucose concentrations and communicate with digitally connected devices.	Same
Principle of operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Measuring range	40 to 400 mg/dL	Same
Site of use	Home	Same
Sensor calibration	Factory calibrated	Same
Sensor hardware	Sensor hardware established for the predicate device	Same
App compatibility	iOS and Android	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	Same

	connected devices (client software) through a cloud-based communication method, the Libre Data Sharing API.	
General Device Characteristic Differences		
Intended use population	Persons age 18 and older not on insulin	Persons with diabetes age 2 and older
Device use	Over the counter	Prescription use
Glucose alarms	No mandatory or optional alarms for low glucose, high glucose, or urgent low glucose	Optional Glucose Alarms: Low Glucose Alarm, High Glucose Alarm Mandatory Glucose Alarms: Urgent Low Glucose Alarm
Interoperable with AID systems	No	Yes
Method to display current glucose result and trend arrow	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.	BLE for glucose data transfer. User-initiated scan via NFC required to display glucose data.
Contraindications against MRI/diathermy/CT	Diathermy	MRI, Diathermy and CT

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 (integrated continuous glucose monitoring system (iCGM)) special controls
- ISO14971- 2019-12 "Medical Devices-Application of Risk Management to Medical Devices"
- IEC 62304 -"Medical Device Software-Software Life Cycle Processes"
- IEC 60601-1-"Medical Electrical Equipment -Part 1: General Requirements for Basic Safety and Essential Performance"
- AAMI TIR69-"Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems"
- AAMI TIR57: 2016- "Principles for medical device security – Risk management"
- IEC 60601-1-2-"Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- ISO 15223-1-"Medical Device-Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied-Part 1: General Requirements"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K222447.

2. Linearity:

   See Assay Reportable Range below.

3. Analytical Specificity/Interference:

   Previously established in K222447.

4. Assay Reportable Range:

   Previously established in K222447.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The FSL2 sensor storage shelf-life of 9 months at 36 to 82 °F within the humidity range of 10 % - 90 % was previously established in K222447.

6. Detection Limit:

   Previously established in K222447.

7. Assay Cut-Off:

   Previously established in K222447.

8. Accuracy (Instrument):

   See comparison studies below.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Previously established in K222447.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Previously established in K222447.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The glucose measurement range of the device is 40 to 400 mg/dL.

F Other Supportive Instrument Performance Characteristics Data:

Software Verification and Validation
Software verification and validation testing was conducted in accordance with established specifications and IEC 62304 and documentation was provided as recommended by FDA Guidance "*Content of Premarket Submissions for Device Software Functions,*" issued June 14, 2023. Results of executed protocols met the acceptance criteria and therefore support that the sensor's embedded software and the Libre Rio App software are acceptable for its intended use.

Cybersecurity
The sponsor 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 "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," issued September 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.

Human Factors
The user interface of the Libre Rio Continuous Glucose Monitoring System has been found to support that the device is substantially equivalent to the predicate device for the intended users, uses, and use environments.

Bench Testing – MR, CT, X-Ray Compatibility
In k233537, bench testing was performed to support the removal of the contraindications against MRI and CT scans for the FSL2. As the sensor component of the subject device is identical to the FSL2, the subject device is labeled MR conditional, and the warning and caution against CT scans and X-Rays is removed in the subject device.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.