May 29, 2024

Abbott Diabetes Care Inc.
Juni Sarkar
Associate Director, Regulatory Affairs
1360 South Loop Road
Alameda, California 94502

Re: K233655
Trade/Device Name: Lingo Glucose System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: SAF
Dated: November 13, 2023
Received: November 14, 2023

Dear Juni Sarkar:

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,

Yiduo Wu -S

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233655

Device Name
Lingo Glucose System

Indications for Use *(Describe)*
The Lingo Glucose System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze and display glucose values in people 18 years and older not on insulin. The Lingo Glucose System helps to detect euglycemic and dysglycemic glucose levels. The Lingo Glucose System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

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.

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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: K233655

Submitter:

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

Applicant Contact: Juni Sarkar
Title: Associate Director, Regulatory Affairs
Phone: (510) 322-1076

Correspondent Contact: Naveen Thuramalla
Title: Divisional Vice President, Regulatory Affairs and New Medical Sensors
Phone: (510) 384-0264

Date Prepared: May 29, 2024

Device Names and Classification:

Name of Device:	Lingo Glucose System
Common Name:	Integrated Continuous Glucose Monitoring System
Product Code	SAF
Regulatory Section:	21 CFR 862.1355
Classification:	Class II
Review Panel:	Clinical Chemistry

Predicate Device

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

Indications for Use:

Indications for Use:

The Lingo Glucose System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze and display glucose values in people 18 years and older not on insulin. The Lingo Glucose System helps to detect euglycemic and dysglycemic glucose levels. The Lingo Glucose System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

Device Description

The Lingo Glucose System (also referred to as 'System') is Abbott's latest biowearable evolution in health technology for glucose measurement. This system encourages users 18 years and older not on insulin, to understand how glucose impacts their body. The Lingo Glucose System includes the Lingo Glucose Biosensor and the Lingo App.

Lingo Biosensor

The Lingo Glucose Biosensor hardware and technology is based on the FDA-cleared FreeStyle Libre 2 (FSL2) sensor (K222447). The Biosensor is a single use disposable on-body Biosensor that incorporates a subcutaneously implanted electrochemical glucose sensor and associated electronics. The Biosensor can be worn for up for 14 days and transmits data to the Lingo App via Bluetooth Low Energy (BLE). Similar to the predicate device, a disposable Biosensor insertion device, consisting of a Biosensor Applicator and Biosensor Pack is used to assemble and apply the Biosensor to the back of the user's upper arm.

Lingo App (iOS)

When downloaded on a compatible smartphone running on iOS, the Lingo App uses Near-Field Communication (NFC) to start a new Biosensor and uses BLE to receive glucose data from the Biosensor. The user can view real-time glucose value, trend arrow, and glucose graph on the app through a glucose range of 55-200 mg/dL. The Lingo App contains on-boarding materials with a self-selection questionnaire that a user must consent prior to using the device. The App does not provide any glucose or system alerts.

Substantial Equivalence

A. Predicate Device Name: FreeStyle Libre 2 Flash Glucose Monitoring System

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

C. Comparison with Predicate: The similarities and differences between the subject and the predicate device are highlighted in the tables below.

Table 1: Similarities with the Predicate Device

Similarities		
	Predicate Device: **FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device:** **Lingo Glucose System (K233655)**
Intended 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**
Compatible sensor	FSL2 sensor is compatible with FreeStyle Libre 2 App	**Same** Lingo Biosensor is compatible with the Lingo App
Compatible operating systems for the App	The App is compatible with Android and iOS enabled smartphones.	**Same** The Lingo App is compatible with iOS enabled smartphones.
Clinical Setting/Sites of Use	Home use	**Same**
Method of Sensor Activation	Near Field Communication (NFC)	**Same**
Method of Data Transfer from Sensor	Bluetooth Low Energy (BLE) for glucose data transfer. User-initiated scan via NFC required to display glucose data	BLE – data automatically transfers without user-initiated scan (streaming data)
Glucose Reading Update Interval	Every 1 minute	**Same**
Real-Time Glucose Information Displayed	Glucose Value, Trend Arrow, and Glucose Graph	**Same**
Sensor Calibration	Factory Calibrated	**Same**
Compatible Sensor Warmup time	1 hour	**Same**
Anatomical Sensor wear locations	Back of the upper arm	**Same**

Similarities		
	Predicate Device: **FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device:** **Lingo Glucose System (K233655)**
Glucose Calculation Algorithm	ADC Glucose Algorithm established for the predicate device	**Same**
System Components	On-body Sensor (User assembles Sensor Applicator and Sensor Container prior to applying the Sensor) Compatible Receiver (App or Reader)	**Same** On-body Sensor (User assembles Biosensor Applicator and Biosensor Container prior to applying the Biosensor) Compatible Receiver (App)
Operating Temperature	50 °F to 113 °F	**Same**
Biosensor Kit Storage Temperature	36 °F to 82 °F	**Same**
Operating and storage relative humidity	10-90%, non-condensing	**Same**
Biosensor water resistance	IP27: Can withstand immersion into 3 ft (one meter) of water for up to 30 minutes. Protected against insertion of objects > 12 mm diameter.	**Same**
Operating and Storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)	**Same**
Radio Frequency	2.402-2.480 GHz BLE; GFSK; 0 dBm EIRP	**Same**

Table 2: Differences with the Predicate Device

Differences		
	Predicate Device: **FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device:** **Lingo Glucose System (K233655)**
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 System is also intended to autonomously communicate with digitally connected devices including automated insulin dosing (AID) system. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.	The Lingo Glucose System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze and display glucose values in people 18 years and older not on insulin. The Lingo Glucose System helps to detect euglycemic and dysglycemic glucose levels. The Lingo Glucose System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.
Availability to user	Prescription use only	Over the counter
Primary display device	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App	Lingo App
Glucose Measuring Range	40 to 400 mg/dL	55 to 200mg/dL

Differences		
	Predicate Device: **FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**	**Subject Device:** **Lingo Glucose System (K233655)**
Sensor Life	Up to 15 days	Up to 14 days
Glucose Alarms	Optional Alarms: Low Glucose and High Glucose Mandatory Alarms: Urgent Low	There are no alarms for the Lingo Glucose System
Location of glucose algorithm	Receiver (Reader or App)	Biosensor
BLE Transmission Range	20 feet unobstructed	33 feet unobstructed
Clinical Application	Management of diabetes mellitus	The Lingo Glucose System is to encourage users to understand the correlation between their glucose values and their nutrition, exercise and daily activities.
Intended Use Population	Persons with diabetes age 2 years and older	The Lingo Glucose System is intended for users 18 years and older not on insulin
Situations Where Fingerstick Test is Required to Confirm Sensor Reading (Adjunctive Use)	• 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	The Lingo Glucose System does not require fingerstick testing based on the intended use of the device.

Comparison of Technological Characteristics with the Predicate Device

The Lingo Glucose System provides the user with real-time glucose measurements between the range of 55-200 mg/dL. Identical to the predicate FSL2 sensor (K222447), the Lingo Glucose Biosensor is designed to measure glucose levels in the user's interstitial fluid through an amperometric electrochemical sensor component. The sensor tail is inserted into the subcutaneous tissue and generates an electrical current via the oxidation of glucose from the interstitial fluid. The real-time glucose measurements are calculated by the Biosensor software and transmit the glucose results to the App through Bluetooth Low Energy (BLE) technology.

At a high level, the subject and predicate devices are based on the same technological elements for glucose measurement and the same glucose calculation algorithm.

Summary of Performance Testing

The following performance characteristics were confirmed to support substantial equivalence:

- Sterility – Based on design similarities between subject Lingo Glucose Biosensor and predicate FSL sensor, electron beam sterilization validation of the Sensor Applicator, which contains the introducer needle and sensor tail, performed on the predicate FSL2 per ISO11137-1 and ISO 11137-2 is applicable to the subject device.

- Shelf-Life, Packaging Integrity, and Shipping – The Lingo Biosensor Kit, including the Biosensor Applicator and Biosensor Pack contained within, has the same shelf life (9 months) as the predicate FreeStyle Libre 2 Sensor Kit and associated contents. This established shelf-life is substantiated to support a storage temperature range of 2°C – 28°C and a humidity range of 10 – 90% RH non-condensing. The predicate FreeStyle Libre 2 Sensor Kit and proposed Lingo Biosensor Kit share the same design and manufacturing process. Therefore, testing used to support the 9-month shelf life of the predicate remains applicable for the Lingo Biosensor Kit, and no additional testing is required.

- Electrical Safety - The basic safety and essential performance of the Biosensor of the FreeStyle Libre 3 System was conducted to demonstrate compliance to IEC 60601-1: 2005(r)2012, IEC 60601-1-6:2010+A1:2013, and IEC 60601-1-11:2015.

- Electromagnetic Compatibility – Electromagnetic compatibility (EMC) testing was performed for the Lingo Glucose System to verify that the system is able to withstand the electromagnetic interference and emissions in compliance with IEC 60601-1-2 and IEC CISPR 11. Wireless coexistence testing was performed to confirm that the Patch remains functional and perform within acceptable limits while in the presence of common radiating electronic devices in accordance with FDA Guidance "*Radio Frequency Wireless Technology in Medical Devices*." The subject device underwent coexistence testing consistent with AAMI TIR69 and ANSI C63.27 and included test challenges from in-band interference sources defined in ANSI C63.27 as well as other expected wireless interference sources from the intended use environment. The Lingo Glucose System also successfully demonstrated compliance with Federal Communication Commission (FCC) Regulations Part 15.225 and Part 15.247, and Federal Aviation Administration (FAA)

Advisory Circular RTCA DO-160.

- Mechanical Engineering – The subject device underwent performance testing at the System level as well as on individual components of the Sensor Applicator. The test results showed that mechanical, electrical, and functional testing all met the acceptance criteria.

- Biocompatibility – Given that the user-contacting material for the Lingo Biosensor (patch mount, adhesive pad, plug components, introducer sharp and sensor component) are identical to those of the predicate, the established biocompatibility evaluation in accordance with with ISO10993-1 and FDA Guidance "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*," for the predicate is applicable to the Lingo Biosensor.

- 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 "*Guidance for the Content of Premarket Submissions for Device Software Functions*." Results of executed protocols met the acceptance criteria and therefore support that the Biosensor's embedded software and the Lingo App software are acceptable for its intended use.

- Cybersecurity – Abbott 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.*" 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.

- Clinical Performance – Abbott conducted a statistical analysis to confirm that the clinical data of the FSL2 System (submitted under K222447) can be leveraged to support the Lingo Glucose System. Considering that the diabetic subjects experience a higher degree of variability in glucose values with larger fluctuations over the measuring range as compared to healthy individuals, the clinical data collected as part of the FSL2 study under K222447 reflects a worst-case scenario for sensor performance. The subject device calculates glucose information identically to the predicate device. System accuracy was demonstrated to meet the iCGM special controls requirements per 21 CFR 862.1355.

- Human Factors – Abbott conducted a risk analysis of the design differences between the subject device compared to the predicate device (K222447) and the newly designed Lingo Glucose App in accordance with ANSI/AAMI/IEC 62366, IEC 60601-1-6, and FDA Guidance "*Applying Human Factors and Usability Engineering to Medical Devices.*" The user interface of the Lingo Glucose System has been found to be adequately designed for the intended users, uses, and use environments.

Conclusion

The Lingo Glucose System has similar technological characteristics and the same intended use as the predicate device. The differences in indications for use and design have been addressed through risk control measures to provide reasonable assurance of the safety and effectiveness of the Lingo Glucose System. Statistical analysis on glucose data accuracy for the Lingo system confirmed that the device met all specified criteria, which supports that the system meets the iCGM special controls for clinical performance set forth in 21 CFR 862.1355, and provides secure, and reliable glucose readings in accordance with the iCGM special controls. 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.