August 26, 2026

Abbott Diabetes Care
Katherine Doll Kanne
Regulatory Affairs Manager
1360 S. Loop Rd.
Alameda, California 94502

Re: DEN250049
Trade/Device Name: Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System
Regulation Number: 21 CFR 862.1354
Regulation Name: Integrated continuous glucose ketone monitoring system
Regulatory Class: Class II
Product Code: SJD
Dated: September 26, 2025
Received: September 29, 2025

Dear Katherine Doll Kanne:

This letter corrects our previous classification order, dated August 25, 2026, to correct an inconsistency in labeling special control (7)(i).

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System, a prescription device with the following indications for use:

> Libre Duo 10 Day is a Continuous Dual Glucose Ketone Monitoring System indicated for the management of diabetes in persons age 2 years and older. It is intended to monitor glucose and ketone (beta-hydroxybutyrate) levels in real-time.
>
> The System also provides alarms, detects trends, tracks glucose and ketone patterns, and aids in the detection of episodes of hyperglycemia, hypoglycemia, and hyperketonemia, facilitating both acute and long-term therapy adjustments, and the system replaces blood glucose testing for diabetes treatment decisions, unless otherwise indicated. Interpretation of system readings should be based on the trends and sequential readings over time. When making therapeutic adjustments, ketone output should be used in conjunction with glucose levels, symptoms, and factors that may affect ketone levels such as eating patterns and exercise.
>
> The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System, and substantially equivalent devices of this generic type, into Class II under the generic name integrated continuous glucose ketone monitoring system.

FDA identifies this generic type of device as:

> **Integrated continuous glucose ketone monitoring system**. An integrated continuous glucose ketone monitoring system (iCGK) is intended to automatically measure glucose and/or ketones in bodily fluids continuously or frequently for a specified period of time. iCGK systems are designed to reliably and securely transmit glucose and/or ketone measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control or ketone fluctuation.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 29, 2025, FDA received your De Novo requesting classification of the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

| Risks to Health | Mitigation Measures |
|---|---|
| Clinical action based on falsely high or falsely low inaccurate glucose values or inaccurate alerts may lead to inappropriate treatment decisions. | Certain design verification and validation, including documentation of certain studies. Certain labeling information, including certain limiting statements and performance characteristics. |

| Risks to Health | Mitigation Measures |
|---|---|
| Clinical action based on falsely high or falsely low inaccurate ketone values, inaccurate ketone trends, or inaccurate alerts may lead to inappropriate treatment decisions. | Certain design verification and validation, including documentation of certain studies. Certain labeling information, including certain limiting statements and performance characteristics. |
| User misunderstanding of device outputs, contraindications, warnings, precautions, or limitations leading to inappropriate user actions that adversely impact diabetes management. | Certain design verification and validation, including documentation of certain studies. Certain labeling information, including certain limiting statements and performance characteristics. |
| The inability to make appropriate treatment decisions when glucose or ketone values are unavailable due to sensor signal drop-out or loss of communication with digitally connected devices. | Certain design verification and validation, including documentation of certain studies. Certain labeling information, including certain limiting statements and performance characteristics. |

In combination with the general controls of the FD&C Act, the integrated continuous glucose ketone monitoring system is subject to the following special controls:

(1) Design verification and validation must include the following:
   (i) Robust clinical data from a clinical study demonstrating the accuracy of the device in the intended use population and throughout the measuring range of the device for each analyte.
   (ii) The clinical data must include a comparison between the iCGK glucose sensor values and blood glucose values in specimens collected in parallel that are measured on an FDA-accepted laboratory-based glucose measurement method that is precise and accurate, and that is traceable to a higher order (e.g., an internationally recognized reference material and/or method).
   (iii) The clinical data must include a comparison between the iCGK ketone sensor values and blood ketone values in specimens collected in parallel that are measured on an FDA-accepted laboratory-based ketone measurement method.
   (iv) Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period.
   (v) Clinical study results for the iCGK glucose sensor in the adult population must meet the following performance requirements:
      (A) For all iCGK glucose sensor measurements less than 70 milligrams/deciliter (mg/dL), the percentage of iCGK measurements within ±15 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 85 percent.
      (B) For all iCGK glucose sensor measurements from 70 mg/dL to 180 mg/dL, the percentage of iCGK measurements within ±15 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 70 percent.
      (C) For all iCGK glucose sensor measurements greater than 180 mg/dL, the percentage of iCGK measurements within ±15 percent of the corresponding blood glucose value

must be calculated, and the lower one-sided 95 percent confidence bound must exceed 80 percent.

(D) For all iCGK glucose sensor measurements less than 70 mg/dL, the percentage of iCGK measurements within ±40 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 98 percent.

(E) For all iCGK glucose sensor measurements from 70 mg/dL to 180 mg/dL, the percentage of iCGK measurements within ±40 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 99 percent.

(F) For all iCGK glucose sensor measurements greater than 180 mg/dL, the percentage of iCGK measurements within ±40 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 99 percent.

(G) Throughout the device measuring range, the percentage of iCGK glucose sensor measurements within ±20 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 87 percent.

(H) When iCGK glucose sensor values are less than 70 mg/dL, no corresponding blood glucose value shall read above 180 mg/dL.

(I) When iCGK glucose sensor values are greater than 180 mg/dL, no corresponding blood glucose value shall read less than 70 mg/dL.

(J) There shall be no more than 1 percent of iCGK glucose sensor measurements that indicate a positive glucose rate of change greater than 1 mg/dL per minute (/min) when the corresponding true negative glucose rate of change is less than -2 mg/dL/min as determined by the corresponding blood glucose measurements.

(K) There shall be no more than 1 percent of iCGK glucose sensor measurements that indicate a negative glucose rate of change less than -1 mg/dL/min when the corresponding true positive glucose rate of change is greater than 2 mg/dL/min as determined by the corresponding blood glucose measurements.

(vi) Clinical study results for the iCGK ketone sensor in the adult population must meet the following performance requirements:

(A) The iCGK ketone sensor accuracy and rate of change performance shall be adequate to ensure clinically acceptable agreement, as determined by FDA.

(B) When iCGK ketone sensor values are less than 0.6 mmol/L, no corresponding blood ketone value shall be above 3.0 mmol/L.

(C) When iCGK ketone sensor values are greater than 3.0 mmol/L, no corresponding blood ketone value shall be less than 0.6 mmol/L.

(vii) Data demonstrating similar accuracy and rate of change performance of the iCGK in the pediatric population as compared to that in the adult population, or alternatively a clinical and/or technical justification for why pediatric data are not needed, must be provided and determined by FDA to be acceptable and appropriate.

(viii) Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically significant gaps in sensor data availability that would prevent any digitally connected devices from achieving their intended use.

(2) Design verification and validation must include a detailed strategy to ensure secure and reliable means of iCGK data transmission to provide real-time glucose and ketone readings at clinically meaningful time intervals to devices intended to receive the glucose and ketone data.
(3) Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the required performance specifications.
(4) The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications.
(5) The device must include appropriate measures to ensure that disposable sensors cannot be used beyond its claimed sensor wear period.
(6) Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose and ketone measurement accuracy.
(7) The required labeling must include a separate description of the following sensor performance data observed in the clinical study for each intended use population and analyte, in addition to separate sensor performance data for each different iCGK insertion or use sites (*e.g.*, abdomen, arm, buttock):
    (i) A description of the iCGK glucose accuracy in the following blood glucose concentration ranges: less than 54 mg/dL, 54 mg/dL to less than 70 mg/dL, 70 to 180 mg/dL, greater than 180 to 250 mg/dL, and greater than 250 mg/dL.
    (ii) A description of the iCGK ketone accuracy in the following blood ketone concentration ranges: less than 0.6 mmol/L, 0.6 to 1.5 mmol/L, greater than 1.5 to 3.0 mmol/L, and greater than 3.0 mmol/L.
    (iii) A description of the accuracy of positive and negative rate of change data.
    (iv) A description of the frequency and duration of gaps in sensor data.
    (v) A description of the true, false, missed, and correct alert rates and a description of the available glucose and ketone concentration alert settings, if applicable.
    (vi) A description of the observed duration of iCGK life for the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the integrated continuous glucose ketone monitoring system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 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 Management System Regulation (QMSR) (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 FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact McKenna Tennant at 301-837-7377.

Sincerely,

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