September 23, 2025

Biolinq Incorporated
Kate Hunter
Senior Director, Regulatory Affairs
10260 Sorrento Valley Rd.
San Diego, California 92121

Re: DEN240080
Trade/Device Name: Biolinq Shine Autonomous Time-in-Range Microsensor
Regulation Number: 21 CFR 862.1359
Regulation Name: Glucose range monitoring system.
Regulatory Class: Class II
Product Code: SFU
Dated: December 26, 2024
Received: December 27, 2024

Dear Kate Hunter:

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 Biolinq Shine Autonomous Time-in-Range Microsensor, a prescription device with the following indications for use:

> Biolinq Shine Autonomous Time-in-Range Microsensor consists of a continuous intradermal glucose sensor with a color-changing indicator light. It is intended to measure, record, and analyze physiologic data using an array of microsensors combined with an accelerometer and ambient light sensor. The qualitative display communicates real-time changes in glucose levels to aid in the management of a disease or condition related to glycemic control in persons 22 years or older not on insulin. An app provides more granular glucose information. It analyzes and correlates this glucose information with meals, rest, and activity levels. Use of the glucose and activity information is designed to facilitate acute behavior and lifestyle modifications. Interpretation of device readings should be based on glucose and activity trends and patterns. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Biolinq Shine Autonomous Time-in-Range Microsensor, and substantially equivalent devices of this generic type, into Class II under the generic name glucose range monitoring system.

FDA identifies this generic type of device as:

> **Glucose range monitoring system.** A glucose range monitoring system (GRM) is intended to automatically measure glucose in the body and provide qualitative or semi-quantitative information about glucose levels or trends continuously or frequently. GRM systems are intended to support general user awareness of glucose ranges related to glycemic control. Outputs from GRM systems do not represent quantitative glucose concentration values and GRM systems are not intended to be used for acute medical decision-making, such as insulin dosing or medication adjustment.

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 December 27, 2024, FDA received your De Novo requesting classification of the Biolinq Shine Autonomous Time-in-Range Microsensor. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Biolinq Shine Autonomous Time-in-Range Microsensor 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 Biolinq Shine Autonomous Time-in-Range Microsensor 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
Mis-categorized semi-quantitative glucose information (falsely higher or falsely lower glucose ranges) leading to inappropriate user actions that adversely impact long-term and short-term glucose management	Certain design verification and validation activities, including documentation of certain studies and other information. 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 long-term and short-term glucose management	Certain design verification and validation activities, including documentation of certain studies and other information. Certain labeling information, including certain limiting statements and performance characteristics.

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

(1) Design verification and validation must include the following:
  (i) Robust clinical data must demonstrate the accuracy of the device for its intended use.
  (ii) The clinical data must include a comparison between GRM outputs 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). Performance must be assessed using appropriate statistical methods for the type of output.
  (iii) The clinical data must be obtained from a clinical study designed to fully represent the performance of the device throughout the intended use population and throughout the measuring range of the device.
  (iv) Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period.
  (v) Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically significant gaps in sensor data availability that would prevent the GRM from achieving its intended use.

(2) Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications as defined in paragraphs (b)(1) and (b)(2) of this section.

(3) 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.

(4) The device must include appropriate measures to ensure that a disposable sensor cannot be used beyond its claimed sensor wear period.

(5) Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and correctly interpret device outputs, contraindications, warnings, precautions, and limitations, as applicable.

(6) The labeling required under § 809.10(b) of this chapter must include a separate description of the following sensor performance data observed in the clinical study performed in conformance with paragraph (b)(1) of this section for each intended use population, in addition to separate sensor performance data for each different GRM insertion or use sites (*e.g.*, abdomen, arm, buttock):
  (i) A description of all device outputs, including glucose data as well as information generated by the device based on the glucose data, their intended purposes, and limitations.
  (ii) A description of the accuracy of the glucose data.
  (iii) A description of the frequency and duration of gaps in sensor data.
  (iv) A description of the observed duration of GRM life for the device.

(v) A statement that the device is not intended for insulin dosing, medication adjustment, or other acute medical decision making.

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 Glucose range 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 Parts 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 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 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 Ghazaleh Esmaili at Ghazaleh.Esmaili@fda.hhs.gov.

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
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