September 11, 2026

Beta Bionics, Inc.
Liz Cooper
Principal Regulatory Affairs Specialist
11 Hughes
Irvine, California 92618

Re: K262763
Trade/Device Name: iLet Dosing Decision Software
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI
Dated: August 3, 2026
Received: August 4, 2026

Dear Liz Cooper:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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); 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 Management System Regulation (QMSR) (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.

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.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

iLet Dosing Decision Software

Please provide your Indications for Use below.

The iLet Dosing Decision Software is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps. A self-monitoring of blood glucose (SMBG) meter may also be used for manual input of blood glucose values to continue insulin dosing for a limited period of time when input from the iCGM is temporarily not available. The iLet Dosing Decision Software autonomously determines and commands an increase, decrease, maintenance, or suspension of all basal doses of insulin and autonomously determines and commands correction doses of insulin based on input from an iCGM, and it autonomously determines and commands meal doses of insulin based on meal announcements. iLet Dosing Decision Software is intended for the management of type 1 diabetes mellitus in people 6 years of age or older. iLet Dosing Decision Software is intended for single patient use and requires a prescription.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Traditional 510(k) Summary: Device Modification
iLet Dosing Decision Software
K262763, Prepared: September 9, 2026

Company: Beta Bionics, Inc.
11 Hughes
Irvine, CA 92618

Contact Person: Liz Cooper
Principal Regulatory Affairs Specialist

Product Trade Name: iLet® Dosing Decision Software

Common Name: Interoperable Automated Glycemic Controller (iAGC)

Classification Name: Interoperable automated glycemic controller

Regulation Number, Device Class and Pro Code: 21CFR 862.1356, Class II, QJI

Predicate Device: iLet® Dosing Decision Software (Beta Bionics, Inc., K232224)

Purpose of this 510(k) Notification:
The modified iLet Dosing Decision Software is compatible with a new user interface and includes an individual meal reset feature that allows a user to reset the learning of an individual meal type (Breakfast, Lunch or Dinner) back to the weight-based default.

Indications for Use:
The iLet Dosing Decision Software is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps. A self-monitoring of blood glucose (SMBG) meter may also be used for manual input of blood glucose values to continue insulin dosing for a limited period of time when input from the iCGM is temporarily not available. The iLet Dosing Decision Software autonomously determines and commands an increase, decrease, maintenance, or suspension of all basal doses of insulin and autonomously determines and commands correction doses of insulin based on input from an iCGM, and it autonomously determines and commands meal doses of insulin based on meal announcements. iLet Dosing Decision Software is intended for the management of type 1 diabetes mellitus in people 6 years of age or older. iLet Dosing Decision Software is intended for single patient use and requires a prescription.

Device Description and Technological Characteristics:
The iLet Dosing Decision Software is an iAGC that autonomously determines and commands an increase, decrease, maintenance, or suspension of all basal doses of insulin and autonomously determines and commands correction doses of insulin based on input from an iCGM, and it autonomously determines and commands meal doses of insulin based on meal announcements. The iLet Dosing Decision Software is intended for the management of type 1 diabetes in people 6 years of age or older.

The iLet Dosing Decision Software works in conjunction with a compatible alternate controller enabled (ACE) pump. The dosing decision software includes adaptive control algorithms that autonomously and continually adapt to the ever-changing insulin requirements of each individual to enable lifelong adaptive learning. The iLet Dosing Decision Software only requires initialization with the user's body mass (body weight).

The iLet Dosing Decision Software does not require carbohydrate counting by the user or the use of carbohydrate-to-insulin ratios. Although the iLet system does not require a user to enter an exact carb amount to calculate and administer a meal bolus, it does require that the user announce the meal

(e.g., breakfast, lunch, dinner) AND provide an estimated carb content as "Usual", "More", or "Less" than is routine for that meal type.

The iLet Dosing Decision Software does not require any information about the user's total daily dose of insulin, basal or long-acting insulin requirements, or insulin correction factors. It is an insulin titration system that requires no insulin-dose determinations by the user or provider. During normal operation, the iLet bionic pancreas (iLet ACE Pump with the iLet Dosing Decision Software installed) autonomously responds every five minutes to a glucose signal, from an iCGM that is worn by the user, by computing a control signal that translates to a dose of insulin, which is intended to be delivered to the user through the subcutaneous (SC) route. The iLet dosing decision software has three insulin controllers (algorithms) running in parallel: an adaptive basal insulin controller, which continually adapts to each individual's basal metabolic need for insulin, an adaptive bolus controller which provides doses that are required above and beyond the basal metabolic needs, and an adaptive meal dose controller which provides insulin in response to a meal announcement.

The iLet is intended to dose insulin based on CGM data. When the CGM is offline for more than 2 hours, the system will revert to Open Loop Mode and dose based on common insulin pump parameters configured by the user's HCP.

Comparison of the Modified Device to the Cleared Device

Element of Comparison	iLet Dosing Decision Software (Predicate Device - K232224)	Subject Device
Device Trade Name	iLet® Dosing Decision Software	Identical
Intended Use	An iAGC which is intended to work with an iCGM and ACE pump to increase, decrease, or suspend delivery of insulin for management of type 1 diabetes	Identical
User Interface	iLet Bionic Pancreas	iLet Mobile App
Communication	Communicates with an ACE pump	Identical
Required user input settings	User's weight Although the iLet system does not require a user to enter an exact carb amount to calculate and administer a meal bolus, it does require that the user announce the meal (e.g., breakfast, lunch, dinner) AND provide an estimated carb content as "Usual", "More", or "Less" than is routine for that meal type. No meal announcement is advised if a meal contains a very small amount of carbohydrates (approximately less than a quarter of usual).	Identical
Maximum Basal Rate	0 – 11.5 units/hr	Identical
BG Target Value	CGM targets of 110 mg/dL, 120 mg/dL and 130 mg/dL	Identical
Maximum Bolus Size	24 units for meal announcement, 30 units overall.	Identical
Maximum Automatic Bolus Size	3 units in response to CGM glucose, 6 units in response to isolated BG when CGM is offline	Identical
Reset Features	Factory Reset: Resets iLet Dosing Decision Software back to factory settings	Addition of individual meal reset feature: Resets the learning of an individual meal type (Breakfast, Lunch or Dinner) back to the weight-based default.

Non-Clinical Testing and Compliance with Special Controls

- **Software Verification and Validation:** Software verification was performed in accordance with ISO 14971:2019, "Medical Devices - Application of Risk Management to Medical Devices," IEC 62304:2006/A1:2016, "Medical Device Software - Software Life Cycle Processes," and FDA guidance, "Content of Premarket Submissions for Device Software Functions" (June 2023).

- **Interoperability:** Interoperability documentation was provided in accordance with FDA Guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices" (September 2017) and the requirements defined by the iAGC special controls in 21 CFR 862.1356.

- **Human Factors Validation:** A human factors and usability engineering process was performed on Subject Devices with compatible CGM and compatible ACE pump in accordance with IEC 62366-1:2015, HE75:2009 and FDA's guidance document, "Applying Human Factors and Usability Engineering to Medical Devices" (February 2016). Results of the human factors validation testing demonstrated that the device is safe and effective for the intended users, intended uses and expected tasks, and intended use environments (K260001).

- **Labeling:** The labeling was reviewed by the FDA. Labeling is sufficient and satisfies applicable requirements of 21 CFR 801, 21 CFR 809, and 21 CFR 880.1356.

- **Special Controls:** The device meets all Special Controls for this product as required by 21 CFR 880.1356 for interoperable automated glycemic controllers, product code QJI.

Clinical Performance:
No new clinical testing was required for this Traditional 510(k) notification.

Design Controls:
The iLet Dosing Decision software was specified and developed by Beta Bionics. Beta Bionics complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as ISO 13485.

Conclusions:
The modified device has been evaluated to be as safe and effective as the Predicate Device. Modifications to the device and labeling do not raise any new or different questions of safety or effectiveness.