September 22, 2023

Beta Bionics, Inc.
Liz Cooper
Senior Regulatory Affairs Specialist
300 Baker Avenue, Suite 301
Concord, MA 01742

Re: K232224
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: July 26, 2023
Received: July 27, 2023

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232224

Device Name
iLet® Dosing Decision Software

Indications for Use *(Describe)*
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.

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.

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510(k) K232224 Summary: Device Modification

iLet Dosing Decision Software

Prepared: September 22, 2023

Company: Beta Bionics, Inc.
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(978) 602-6239

Contact Person: Liz Cooper
Senior Regulatory Affairs Specialist
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(732) 275-5848

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., K220916)

Purpose of 510(k) Notification:
The User Guide and Quick Reference Guide are being updated to expand the indications for use of the iLet bionic pancreas with U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge to include people 6 years of age or older with diabetes mellitus.

No changes have been made to the technological characteristics of the device.

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 Principle of Operation:
The iLet Dosing Decision Software is an iAGC indicated for the management of type 1 diabetes mellitus. It 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 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 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. In the events where CGM stops providing glucose data to the iLet, the iLet Dosing Decision Software BG-run mode feature will serve to temporarily continue insulin delivery. BG-run mode will determine and command basal insulin based on past requirements and will allow announcement of meals and entry of fingerstick BG measurements, which will be treated as iCGM data and may result in commanding administration of insulin or temporary suspension of basal insulin. BG-run mode use should always be for the shortest duration possible with the goal to resume CGM.

Comparison of the Modified Device to the Cleared Device

Element of Comparison	iLet Dosing Decision Software (Predicate Device - K220916)	Subject Device
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
Fiasp Age Indication	People 18 years of age or older	People 6 years of age or older
Communication	Communicates with an ACE pump	Identical
Required user input settings	User's weight	Identical

Element of Comparison	iLet Dosing Decision Software (Predicate Device - K220916)	Subject Device
	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).	
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

Discussion of Clinical Testing

The Insulin-Only Bionic Pancreas Extension Study was an extension study for adults and children >6 years old with type 1 diabetes (T1D) who participated in the Standard Care Group (control group) in a prior 13-week multi-center, parallel group randomized controlled trial (RCT) that compared the SC Group with a group using the insulin-only (IO) configuration of the iLet Bionic Pancreas (BP) System. In the Extension Study, the RCT SC group had the opportunity to use the IO configuration of the iLet BP System for 13 weeks. The clinical study used to support the safety of Fiasp® PumpCart® (insulin aspart) in a prefilled 1.6mL cartridge with the iLet was obtained in a 13-week, single-arm clinical study that included 46 users 6-17 years of age. The clinical study was an extension study of the insulin only RCT. Participants of the SC arm of the RCT transitioned to use of the iLet with Fiasp in the extension phase, a 13-week single-arm intervention trial (extension of randomized controlled trial [RCT] for the control group) with 90 total participants with Type 1 diabetes at 16 clinical sites in the United States (46 participants 6-17 years of age).

Methods: Participants were trained on use of the BP. Participants 6-17 years of age used U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge.

Phone contacts occurred after 1-2 days and 7 (±2) days and visits occurred at 2 weeks (±4 days), 6 weeks (±4 days), 10 weeks (±4 days), and 13 weeks (±4 days). Visits could be conducted virtually. At the 13-week visit, a blood sample was obtained for central lab HbA1c determination and psychosocial questionnaires were completed.

Endpoints: All participants who initiated use of the BP with Fiasp were included in the analyses. The 13-week HbA1c measurement at the end of the RCT and the 13 weeks of CGM data during the RCT were used as baseline metrics for the analyses. For outcomes, HbA1c was measured at the end of 13 weeks and CGM data were collected over the full 13 weeks.

Key outcomes:

- HbA1c

- Mean CGM glucose
- Time 70-180 mg/dL
- Time >180 mg/dL
- Time >250 mg/dL
- Hyperglycemic event rate
- Time <70 mg/dL
- Time <54 mg/dL
- Hypoglycemic event rate
- Standard deviation of mean CGM glucose
- Coefficient of variation

Other Key Outcomes:

- Psychosocial questionnaires
- Insulin metrics
- Other HbA1c and CGM metrics

Participants 6-17 Years of Age Results: 46 of the 48 participants 6-17 years of age initiated BP with Fiasp and were included in this analysis. In the 6-17 years of age cohort of the extension study which used Fiasp with the iLet, the study found a decrease in HbA1c from baseline to 13 weeks of 0.56%. There was an increase in time in range (TIR) from baseline by 12.0% and mean glucose decreased by 18 mg/dL. These changes occurred without an increase in CGM-measured time <54 mg/dL (decreased 0.15%), which was 0.67% at baseline and decreased to 0.54% over the 13 weeks of the study. Time <70 mg/dL showed a slight decrease of 0.82% from baseline.

Conclusions

The preceding summary of clinical testing demonstrates that the performance of the subject device with the use of fast-acting insulin lispro (Fiasp) in patients 6 years of age or older in terms of safety and effectiveness is comparable to the predicate device. The modified device has been evaluated to be as safe and effective as the Predicate Device.