510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K262763

B Applicant

Beta Bionics, Inc.

C Proprietary and Established Names

iLet® Dosing Decision Software

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	II	21 CFR 862.1356 - Interoperable automated glycemic controller	CH – Clinical Chemistry

E Purpose for Submission:

Modifications to the individual meal reset feature.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

Do not use the iLet Dosing Decision Software if you are unable or unwilling to test blood glucose (BG) levels with an SMBG meter when input from the iCGM is not available.

Do not use the iLet Dosing Decision Software if you are unable or unwilling to recognize and respond to safety alerts.

Do not use the pump system if you are taking hydroxyurea, also known as Hydrea. This medication is sometimes used in the treatment of blood disorders and some kinds of cancer. The use of hydroxyurea can result in falsely elevated sensor glucose readings. The pump system relies on sensor glucose readings to adjust insulin, provide insulin doses, and provide high and low glucose alerts. If the pump system receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and potential errors in diabetes management, such as too much insulin being delivered. Hydroxyurea can also result in errors when reviewing, analyzing, and interpreting historical patterns for assessing glucose control.

Do not use the iLet Dosing Decision Software in people under 6 years of age. The iLet Dosing Decision Software has not been studied in these populations.

Do not use the iLet Dosing Decision Software in people who are pregnant, on dialysis or critically ill. The iLet Dosing Decision Software has not been studied in these populations.

The system should NOT be used in hospitalized people as the safety of the technology has not been evaluated in this population.

The iLet Dosing Decision Software is only for use with U-100 insulin lispro (Humalog), U-100 insulin aspart (Novolog), U-100 insulin aspart (Fiasp), U-100 insulin aspart-xjhz (Kirsty), or U-100 insulin aspart in prefilled 1.6mL cartridge (Fiasp® PumpCart® (insulin aspart)).

The iLet Dosing Decision Software is only for use with a compatible iCGM. When using the iLet Dosing Decision Software, wear an iCGM.

Remove the pump, steel infusion set (if applicable), CGM sensor, and CGM transmitter before undergoing radiation therapy, Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment procedures. Exposure of the pump, steel infusion set (if applicable), CGM sensor, or CGM transmitter to any of these may damage them.

Do not expose your pump, steel infusion set (if applicable), CGM transmitter, or CGM sensor to equipment used in procedures for Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming, Cardiac Catheterization, or Nuclear Stress Test.

The iLet Mobile App is compatible with the iOS platform and Android platform. The iLet Mobile App provides the ability to perform over-the-air updates and / or pull data from an Beta Bionics pump to share with the Beta Bionics Cloud.

III Device Description

The iLet Dosing Decision software is intended for use by people with diabetes. The iLet Dosing Decision software works in conjunction with a compatible alternate controller enabled (ACE) pump. The iLet Dosing Decision Software requires initialization with the user's body mass (body weight), as well as meal announcements. When initiating a meal announcement with the iLet Dosing Decision Software, the user qualitatively approximates carbohydrate content (meal size) relative to the usual carbohydrate content for each of the three meal types (breakfast, lunch, or dinner). The iLet Dosing Decision Software autonomously determines the size of the insulin dose in response to a meal announcement by the user.

The iLet is intended to dose insulin based on CGM data. During normal operation, the iLet Dosing Decision Software installed on a Beta Bionics pump autonomously responds every five minutes to a glucose signal, from an iCGM that is worn by the user. 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.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

iLet® Dosing Decision Software

B Predicate 510(k) Number(s):

K232224

C Comparison with Predicate(s):

Device & Predicate Device(s):	K262763	K232224
Device Trade Name	iLet® Dosing Decision Software	iLet® Dosing Decision Software
General Device Characteristic Similarities		

Intended Use/Indications For Use	Intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin, as well as command correction doses, based on glucose values.	Same
Intended patient population	For the management of diabetes mellitus in persons 6 years and older.	Same
General Device Characteristic Differences		
User Interface	iLet Mobile App, or iLet Bionic Pancreas	iLet Bionic Pancreas
Meal Reset Features	Addition of individual meal reset feature: Resets the learning of an individual meal type (Breakfast, Lunch or Dinner) back to the weight-based default.	Factory Reset: Resets the learning of meals, basal and correction doses back to the factory settings.

V Standards/Guidance Documents Referenced:

- Special controls under 21 CFR 862.1356
- ISO 14971:2019 – Medical devices: Application of risk management to medical devices
- IEC 62304:2006/A1:2016 – Medical device software: Software life cycle processes
- FDA Guidance: Content of Premarket Submissions for Device Software Functions (2023)
- FDA Guidance: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (2017)
- FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices (2016)
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)

VI Performance Characteristics:

A. Non-Clinical Performance

Non-clinical performance was not applicable to the modifications made in this submission.

B. Clinical Studies

Clinical studies were not applicable to the modifications made in this submission.

C. Other Supportive Device Performance Characteristics Data

1. Cybersecurity
   Detailed information on cybersecurity of the device was reviewed and found to be acceptable under Mint ACE Pump (K260001). Beta Bionics provided a software bill of materials, which provided details on all software used in the device and the hardware platform that the device was installed on. This included all manufacturer-developed, commercially licensed, open source, and off-the shelf software components (including firmware as relevant), along with an identification of the hardware runtime environment in which each resides, with relevant version and/or model information, as well as details on whether each component was actively supported by its manufacturer or legacy licensed.

2. Interoperability
   A plan and approach for interoperability were provided for integration of CGM, iAGC and Mobile App and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices.

3. Human Factors
   Beta Bionics executed a human factors and usability engineering process that followed and complied with FDA-recognized standards IEC62366:2015-1 and HE75:20252009 as well as the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices – Issued February 3, 2016. Human Factors validation study testing was conducted with the Mint System (Mint ACE Pump with the iLet Dosing Decision Software installed, and Beta Bionics App) in a simulated use condition, including associated training and accompanying documentation. All critical tasks were tested in the validation study. Results of the study demonstrated that the device could be used safely by intended users in the intended use environment when used in combination with a digitally connected device.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.