510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K232224

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	Class II	21 CFR 862.1356 – Interoperable Automatic Glycemic Controller	CH – Clinical Chemistry

E Purpose for Submission:

Modifications to the device Instructions for Use to add U-100 Fiasp, in the Fiasp PumpCart prefilled cartridge, as a compatible insulin for ages 6 years and older.

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 iLet safety alerts.

Do not use the iLet 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 iLet System relies on sensor glucose readings to adjust insulin, provide insulin doses, and provide high and low glucose alerts. If the iLet 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 ACE Pump and Dosing Decision Software in people under 6 years of age. The iLet ACE Pump and Dosing Decision Software have 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 insulin U-100 lispro (Humalog), insulin U-100 aspart (Novolog), or insulin U-100 aspart (Fiasp).

Do not use the iLet Dosing Decision Software with the U-100 Fiasp in individuals under 18 years of age. The iLet Dosing Decision Software has not been studied with the U-100 Fiasp in these populations.

The iLet Dosing Decision Software is only for use with the Dexcom G6 iCGM. When using the iLet device, wear an iCGM.

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

Do not expose your iLet device, steel infusion set, 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 Go App is compatible with the iOS platform. The iLet Go App provides the ability to perform over-the-air updates and / or pull data from an iLet device to share with the Beta Bionics Cloud. The iLet Go App is not currently compatible with Android or other platforms.

If your CGM is offline for an extended period of time, dosing will stop and you should switch to alternative therapy until you are able to reconnect to a CGM sensor. A countdown timer will appear before dosing would stop.

III Device Description

The iLet Dosing Decision software is part of the iLet Bionic Pancreas and 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 determine the size of the insulin dose in response to a meal announcement by the user.

The iLet Dosing Decision software works to control glucose to a user-set glucose target of "lower" (110 mg/dL), "usual" (120 mg/dL), or "higher" (130 mg/dL) within the device settings. Users can also set glucose targets specific for sleep.

The iLet Dosing Decision software also includes a feature, called "BG-Run mode", which enables the device to continue insulin delivery in the event CGM-data is unavailable. Use of the feature, however, should be temporary and always for the shortest duration possible, with the goal to resume CGM-guided insulin dosing as soon as possible.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

iLet® Dosing Decision Software

B Predicate 510(k) Number(s):

K220916

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232224	K220916
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
General Device Characteristic Differences		
Fiasp Age Indication	6 years and older	18 years and older

V Standards/Guidance Documents Referenced:

ISO 14155:2020 - Clinical investigation of medical devices for human subjects - Good clinical practice

VI Performance Characteristics:

A. Analytical Performance

The analytical performance of the iLet Dosing Decision Software was previously established and described in the public decision summary for K220916.

B. Other Supportive Instrument Performance Characteristics Data

1. Summary of Clinical Testing

The sponsor conducted a 13-week, single-arm extension study for 48 subjects aged 6 to 17

years old with type 1 diabetes (T1D) at 16 clinical sites within the United States who had participated in the Standard Care Group (SC/control group) in the Bionic Pancreas (BP) Pivotal trial, a prior 13-week multi-center, parallel group randomized control trial (RCT). In the extension study, the RCT SC group was given the opportunity to use the insulin-only configuration of the iLet BP system. All participants 6-17 years old (at time of consent for the RCT) used study-provided U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge during the Extension Study.

Observed Results

Mean Change in HbA1c from Baseline to 13 Weeks (6 – 17 Years)			
	Baseline (SC)	**Week 13 (BP-F)**	**Change from Baseline to Week 13**
Overall (*SD*)	N = 45 7.8 (*1.1*)	N = 43 7.2 (*0.7*)	N = 42* -0.56 (*0.69*)
6 – 12 Years (*SD*)	N = 23 8.0 (*0.9*)	N = 22 7.2 (*0.5*)	N = 21 -0.65 (*0.68*)
13 – 17 Years (*SD*)	N = 22 7.6 (*1.3*)	N = 21 7.1 (*0.8*)	N = 21 -0.47 (*0.71*)

**Out of 46 subjects 6 – 17 years old who were on Fiasp, 1 subject had missing HbA1c data at baseline and 3 subjects had missing HbA1c data during follow-up for a total of 4 subjects missing data, therefore change from baseline to Week 13 was analyzed in a total of 42 subjects.*

CGM Outcomes (6 – 17 Years)			
	Baseline (SC)	**Week 13 (BP-F)**	**Change from Baseline to Week 13**
Overall	N = 46	N = 45	N = 45
Hours of CGM Data (*SD*)	2042 (*132*)	1877 (*270*)	-
% Time in Range 70 – 180 mg/dL (*SD*)	51% (*16%*)	63% (*10%*)	12.0% (*11.8%*)
Mean glucose (mg/dL) (*SD*)	187 (*34*)	168 (*16*)	-18 (*24*)
% Time > 180 mg/dL (*SD*)	46% (*17%*)	35% (*10%*)	-11.2% (*12.3%*)
% Time >250 mg/dL (*SD*)	21.2% (*14.7%*)	11.6% (*6.5%*)	-9.8% (*10.7%*)
% Time <70 mg/dL (*SD*)	3.1 (*2.5*)	1.7 (*1.5*)	-1.5 (*1.8*)
% Time <54 mg/dL (*SD*)	0.67% (*0.90%*)	0.54% (*0.51%*)	-0.15% (*0.69%*)
6 – 12 Years	N = 24	N = 24	N = 24
Hours of CGM Data (*SD*)	2035 (*150*)	1902 (*319*)	-

6 – 12 Years	N = 24	N = 24	N = 24
% Time in Range 70 – 180 mg/dL (*SD*)	49% (*15%*)	62% (*6%*)	13.1% (*13.6%*)
Mean glucose (mg/dL) (*SD*)	187 (*30*)	166 (*1*)	.20 (*26*)
% Time > 180 mg/dL (*SD*)	47% (*16%*)	35% (*6%*)	.12.6% (*14.1%*)
% Time >250 mg/dL (*SD*)	22.5% (*12.6%*)	11.4% (*3.8%*)	-11.1 (*11.2%*)
% Time <70 mg/dL (*SD*)	3.43% (*2.83%*)	2.91% (*1.54%*)	-0.52% (*2.15%*)
% Time <54 mg/dL (*SD*)	0.88% (*1.09%*)	0.77% (*0.54%*)	-0.10% (*0.84%*)
13 – 17 Years	N = 22	N = 21	N = 21
Hours of CGM Data (*SD*)	2049 (*113*)	1848 (*203*)	-
% Time in Range 70 – 180 mg/dL (*SD*)	52% (*18%*)	63% (*12%*)	10.8% (*9.4%*)
Mean glucose (mg/dL) (*SD*)	186 (*39*)	170 (*21*)	-16 (*23*)
% Time > 180 mg/dL (*SD*)	45% (*19%*)	36% (*13%*)	-9.7% (*9.9%*)
% Time >250 mg/dL (*SD*)	19.8% (*16.9%*)	11.8% (*8.7%*)	-8.4% (*10.2%*)
% Time <70 mg/dL (*SD*)	2.31% (*2.39%*)	1.24% (*0.64%*)	-1.16% (*2.10%*)
% Time <54 mg/dL (*SD*)	0.45% (*0.58%*)	0.27% (*0.19%*)	-0.20% (*0.48%*)

Safety Results

Summary of Adverse Events (6 – 17 Years)			
	Overall	**6 – 12 Years**	**13 – 17 Years**
Number of participants	46	24	22
Severe Hypoglycemic (SH) Events[a]			
Number of Events	0	0	0
Participants with ≥1 event	0 (0%)	0 (0%)	0 (0%)
Number of events per subject			
0	46 (100%)	24 (100%)	22 (100%)
1	0 (0%)	0 (0%)	0 (0%)
Incident rate per 100 person-years	0	0	0
Diabetic Ketoacidosis Events[b]			

Number of Events	1	1	0
Participants with ≥1 event	1 (2%)	1 (4%)	0 (0%)
Number of events per subject			
0	45 (98%)	23 (96%)	22 (100%)
1	1 (2%)	1 (4%)	0 (0%)
Incident rate per 100 person-years	8.9	16.9	0.0
Other Serious Adverse Events (SAEs)[c]			
Number of Events	1	0	1
Participants with ≥1 event	1 (2%)	0 (0%)	1 (5%)
Number of events per subject			
0	45 (98%)	24 (100%)	21 (95%)
1	1 (2%)	0 (0%)	1 (5%)
Incident rate per 100 person-years	8.9	0.0	18.9

a - A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

b - A hyperglycemic event is classified as DKA if the following are present: a) symptoms such as polyuria, polydipsia, nausea, or vomiting; b) serum ketones >1.5 mmol/L or large/moderate urine ketones; c) either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15; and d) treatment provided in a health care facility.

c - A serious adverse event is defined as any untoward medical occurrence that a) results in death, b) is life-threatening, c) requires inpatient hospitalization of prolongation of existing hospitalization, d) results in persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions (sight threatening), e) is a congenital anomaly or birth defect, or f) is considered a significant medical event by the investigator based on medical judgment.

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.