510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253976

B Applicant

Beta Bionics, Inc.

C Proprietary and Established Names

iLet ACE Pump

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	II	21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump	CH - Clinical Chemistry

E Purpose for Submission:

Modification to the iLet ACE Pump cleared under K252770 with the following changes:

- Implementation of a color LCD display, updated charging electronics for efficiency, replaced end-of-life components, and a reduction in the size of the iLet ACE Pump by removing unused space occupied by the alternate drug channel.
- Implementation of a Pause Insulin feature that allows a user to temporarily suspend insulin delivery analogous to shutting off the pump and manually reconnecting.
- The User Guide and Quick Reference Guide are being updated to indicate that the iLet bionic pancreas can be used with the vial presentation of U-100 Fiasp (insulin aspart).
- Establish a predetermined change control plan for addition of a new FDA-approved insulin product presentation of a previously FDA-approved insulin product to the list of compatible insulin products.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The iLet ACE Pump is an alternate controller enabled (ACE) pump intended to deliver insulin under the skin based on input from an integrated continuous glucose monitor (iCGM) and an interoperable automated glycemic controller (iAGC), in people 6 years of age or older with diabetes mellitus. The iLet ACE Pump is intended for single-person use; it is not to be shared.

C Special Conditions for Use Statement(s):

Rx – For prescription use only.

Do not use the iLet ACE Pump and 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 ACE Pump and 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. The use of 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 who are pregnant, on dialysis or critically ill. The iLet ACE Pump and Dosing Decision Software have not been studied in these populations.

The iLet System is only for use with a compatible iCGM. When using the iLet Device, wear an iCGM.

Do not expose your iLet System, including your iLet Device and steel infusion set to X-ray (screening at airports or other facilities and procedures), Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI), or Positron Emission Tomography (PET) scan.

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

Your iLet System, including your iLet Device and steel infusion set, is not magnetic resonance (MR) safe. Your iLet System must be left outside of the procedure room if you are receiving an MRI scan.

Do not expose your iLet Device and steel infusion set to equipment used in procedures for Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming, Cardiac Catheterization, or Nuclear Stress Test.

Depending on the equipment being used during general anesthesia, your iLet System may need to be removed. You do not need to remove iLet System components for electrocardiograms (EKGs) or colonoscopies. Metal detectors and body scanners at airports are also acceptable. Remove your iLet System prior to any laser surgery as some lasers can create interference and cause your iLet System to alert you.

Your iLet System is for single patient use only. Sharing any part of your iLet System may lead to transfer of germs, infection, or over/under delivery of insulin.

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The iLet ACE Pump and Dosing Decision Software were evaluated in an outpatient setting for home use. The system has not been evaluated in hospitalized people.

Avoid exposure of your iLet Device to temperatures below 40°F (5°C) or above 104°F (40°C). Insulin can freeze at low temperatures and degrade at high temperatures. Insulin exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of your iLet System.

III Device Description

The iLet ACE Pump with the iLet Dosing Decision Software is a component of the iLet System that consists with the following:

a. The iLet ACE Pump: automatically delivers insulin subcutaneously based on input from an integrated continuous glucose monitor (iCGM) and/or a self-monitoring blood glucose (SMBG) meter, and an interoperable automated glycemic controller (iAGC). In the absence of input from an iCGM, the iAGC can instead use blood glucose entries from an SMBG meter. Insulin is injected from the iLet ACE Pump through an infusion set.
b. iLet Cartridge: Glass container with a soft membrane and a red rubber plunger is filled with insulin and inserted into the iLet ACE Pump.
c. Insulin Infusion Set: Contains the insulin infusion set base, flexible tubing, and inserter, and is used to attach the insulin infusion set base to user body.

The iLet ACE Pump is an alternate controller enabled (ACE) pump intended to deliver insulin under the skin based on input from an integrated continuous glucose monitor (CGM) and an interoperable automated glycemic controller (iAGC) in people 6 years of age or older with diabetes mellitus. The iLet ACE Pump gets glucose readings from the CGM every 5 minutes and the iAGC uses that information as one of the inputs to calculate the person's insulin needs.

The iLet ACE Pump includes a motor–drivetrain pumping mechanism, which independently actuates the delivery of insulin from a cartridge that is separately loaded into the iLet. Insulin is injected under the skin via continuous infusion. The infusion set must be placed at least 3 inches away from the CGM sensor.

The iLet ACE Pump has a touchscreen where users can access the meal announcement feature, view their blood glucose level, and respond to any alerts. The circular icon shown in the middle

of the screen rotates when the iLet device is running. The iLet ACE Pump also has a Sleep/Wake button on the top that the user touches to turn the touchscreen and backlight on and off.

The iLet ACE Pump has a wirelessly rechargeable battery and is designed to be used by a single person and have a useful life of at least 4 years. The iLet is charged on a wireless charging pad which comes with the device. The Luer connector and drug cartridge need to be changed every 3 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

iLet ACE Pump

B Predicate 510(k) Number(s):

K252770

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253976	K252770
Device Trade Name	iLet ACE Pump	iLet ACE Pump
General Device Characteristic Similarities		
Intended Use/Indications For Use	An alternate controller enabled (ACE) pump intended to deliver insulin under the skin based on input from an integrated continuous glucose monitor (iCGM) and an interoperable automated glycemic controller (iAGC), in people 6 years of age or older with diabetes mellitus.	Same
General Device Characteristic Differences		
Drug Use	U-100 Insulins: NovoLog, Kirsty, Humalog, Fiasp, and Fiasp PumpCart.	U-100 Insulins: NovoLog, Kirsty, Humalog, and Fiasp PumpCart.
Pause Insulin feature	Present	Not present
Display size and color	Color: 49W × 91L × 16H mm	Monochromatic: 59W × 91L × 15H mm

Predetermined Change Control Plan (PCCP):
In addition to the similarities and differences between the candidate and predicate devices listed in the table above, the candidate device has an authorized PCCP to add a new, prespecified insulin product presentation of a previously FDA-approved insulin product to the list of compatible insulin products. See Section VI.C for more information.

V Standards/Guidance Documents Referenced:

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes
- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- AAMI TIR69:2017/(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems

VI Performance Characteristics:

A. Non-Clinical Performance

1. Basal Delivery Accuracy

To assess basal delivery accuracy, 44 (29 new and 15 aged), 30 (15 new and 15 aged), and 30 (15 new and 15 aged) pumps were respectively tested at low (0.1U/hr), medium (1.0U/hr), and high (10.0 U/hr) basal rates. The aged pumps went through simulated use cycles representing four (4) years of use. For both aged and unaged pumps, all cartridges were new. Water used as a substitute for insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warmup period.

Table 1.a: Amount of fluid delivered after 1, 6, and 12 hours with 0.1 U/hr (low) basal rate setting (new pump)

0.1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.1 U**	**0.6 U**	**1.2 U**
Median amount delivered	0.09 U	0.56 U	1.12 U
[min, max]	[0.00, 0.13]	[0.29, 0.67]	[0.79, 1.31]

Table 1.b: Amount of fluid delivered after 1, 6, and 12 hours with 0.1 U/hr (low) basal rate setting (aged pump)

0.1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.1 U**	**0.6 U**	**1.2 U**
Median amount delivered	0.09 U	0.55 U	1.11 U
[min, max]	[0.00, 0.12]	[0.24, 0.64]	[0.71, 1.23]

Table 2.a: Amount of fluid delivered after 1, 6, and 12 hours with 1.0 U/hr (medium) basal rate setting (new pump)

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered	0.99 U	5.95 U	11.90 U
[min, max]	[0.80, 1.17]	[5.50, 6.15]	[11.23, 12.15]

Table 2.b: Amount of fluid delivered after 1, 6, and 12 hours with 1.0 U/hr (medium) basal rate setting (aged pump)

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered	0.99 U	5.95 U	11.93 U
[min, max]	[0.79, 1.28]	[5.47, 6.28]	[11.17, 12.22]

Table 3.a: Amount of fluid delivered after 1, 6, and 12 hours with 10.0 U/hr (high) basal rate setting (new pump)

10 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**10 U**	**60 U**	**120 U**
Median amount delivered	9.92 U	59.52 U	118.97 U
[min, max]	[9.20, 10.50]	[58.36, 60.49]	[117.43, 120.46]

Table 3.b: Amount of fluid delivered after 1, 6, and 12 hours with 10.0 U/hr (high) basal rate setting (aged pump)

10 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**10 U**	**60 U**	**120 U**
Median amount delivered	10.00 U	60.04 U	120.02 U
[min, max]	[9.74, 10.19]	[59.29, 60.54]	[118.65, 120.84]

2. Bolus Delivery Accuracy

To assess bolus delivery accuracy, 15 new and 15 aged pumps for a total of 30 unique pumps were tested for each bolus size by delivering minimum, intermediate, and maximum bolus amounts (0.5, 5, and 30 Units). The aged pumps went through simulated use cycles representing four (4) years of use. For both aged and unaged pumps, all cartridges were new. Water used as a substitute for insulin was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy. The number of total and consecutive boluses delivered in this testing for each delivery volume is described in Table 4 below:

Table 4: Summary of bolus testing protocol

Bolus size (units)	Pumps	Number of pumps tested	Consecutive boluses per pump	Total boluses
0.5 units	New	15	25	375
	Aged	15	25	375
5 units	New	15	25	375
	Aged	15	25	375
30 units	New	15	16	240
	Aged	15	16	240

The actual bolus volume delivered was compared to the expected bolus volume for minimum, intermediate, and maximum boluses. Tables 5-7 below show the number (and %) of boluses within the specified range of each target bolus volume.

Table 5.a: Amount of fluid delivered after a 0.5 U bolus request (new pump)

Units delivered after a 0.5 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/375 -	2/375 -	5/375 (1.3%)	33/375 (8.8%)	319/375 (85.1%)	16/375 (4.3%)	2/375 (0.5%)	0/375 -	0/375 -	0/375 -

Table 5.b: Amount of fluid delivered after a 0.5 U bolus request (aged pump)

Units delivered after a 0.5 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/375 -	2/375 -	2/375 (0.5%)	29/375 (7.7%)	319/375 (85.1%)	22/375 (5.9%)	3/375 (0.8%)	0/375 -	0/375 -	0/375 -

Table 6.a: Amount of fluid delivered after a 5 U bolus request (new pump)

Units delivered after a 5.0 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/375 -	0/375 -	0/375 -	0/375 -	375/375 (100%)	0/375 -	0/375 -	0/375 -	0/375 -	0/375 -

Table 6.b: Amount of fluid delivered after a 5 U bolus request (aged pump)

Units delivered after a 5.0 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/375 -	0/375 -	0/375 -	6/375 (1.6%)	369/375 (98.4%)	0/375 -	0/375 -	0/375 -	0/375 -	0/375 -

Table 7.a: Amount of fluid delivered after a 30 U bolus request (new pump)

Units delivered after a 30.0 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/240 -	0/240 -	0/240 -	0/240 -	240/240 (100%)	0/240 -	0/240 -	0/240 -	0/240 -	0/240 -

Table 7.b: Amount of fluid delivered after a 30 U bolus request (aged pump)

Units delivered after a 30.0 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/240 -	0/240 -	0/240 -	0/240 -	240/240 (100%)	0/240 -	0/240 -	0/240 -	0/240 -	0/240 -

3. Occlusion Detection

Occlusion detection testing was conducted using 29 pumps and 3 delivery profiles: 5U Bolus, 0.1U/hr basal, and 1U/hr Basal. The pumps were tested for the time between occlusion and pump alarm sequentially and for the 3 delivery profiles. The typical time to occlusion detection in the table below is the average for the samples measured and the maximum time is the absolute maximum.

Table 8: Occlusion detection testing

	Typical time to occlusion detection	**Maximum time to occlusion detection**
5 U Bolus	29 seconds	1 minute
1 U/hr basal	2 hours and 30 minutes	3 hours and 20 minutes
0.1 U/hr Basal	25 hours and 2 minutes	37 hours and 30 minutes

The insulin delivered until an occlusion alarm occurred was within the acceptance criteria of 4U.

B. Clinical Studies:

NA

C. Other Supportive Device Performance Characteristics Data

4. Additional Bench Testing
   In addition to the performance testing described above, other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified, including:
   a. Delivery accuracy was tested at high and low set points for temperature, pressure, and humidity with 29 unique pumps.
   b. Delivery accuracy was tested under a total of 21 static and dynamic environmental profiles of temperature and pressure with 3 unique pumps.
   c. Delivery accuracy was tested with 29 unique pumps after exposure to drop and shock and vibe.
   d. Delivery accuracy and connectivity were tested with 3 unique pumps after exposure to stressors sequentially: chemicals, shock, vibe, drop, and ingress of water.
   e. Ingress of water was tested to achieve IPX8 using 15 pumps.

5. Insulin Compatibility
   The provided information supports compatibility with the vial presentation of U-100 Fiasp (insulin aspart) for up to 3 days.

6. Software
   The software documentation provided was determined to be adequate to support substantial equivalence.

7. Electromagnetic compatibility and Electrical Safety
   Electromagnetic compatibility and electromagnetic immunity testing was performed for the pump according to IEC 60601-4-2. All tests demonstrated that the device would perform as expected in the home healthcare environment.

8. Wireless Coexistence
   Evaluated per ANSI/IEEE C63.27-2021, as well as range and household coexistence protocols. Reports demonstrated robust BLE communication in coexistence, range, and household environments with no loss of safety or performance.

9. Leveraged Information
   a. Risk analysis: The System Risk Analysis and Risk management Plan and Report were leveraged from the predicate device cleared under K252770.
   b. Biocompatibility: Since there are no changes to tissue contacting materials in this submission, biocompatibility testing was leveraged from previous versions of the device cleared under K223846 and K220916.
   c. Sterility: Sterility was leveraged from previous versions of the device cleared under K252770.
   d. Human Factors: Human Factors testing was leveraged from the original device cleared under K220916. An evaluation of the Human Factors decision flow chart was performed for the device with the color display and the Pause Insulin Feature. There are no new critical tasks introduced, nor are existing critical tasks impacted. The existing Human Factors validation results continue to be valid.
   e. Cybersecurity: Cybersecurity of the device is unchanged compared to the device cleared under K252770.

f. Interoperability: Interoperability risk assessment is unchanged compared to the device cleared under K252770.

10. Predetermined Change Control Plan (PCCP)

The PCCP documents how the labeling for the iLet pump will be modified to add a new, pre-specified FDA-approved presentation of a previously FDA-approved insulin product to the list of compatible insulin products.

The performance evaluation methods for validating this modification are described below:

- In-use compatibility testing between the iLet insulin pump and the new insulin product presentation will be conducted following a specified protocol. The same protocol was previously used to establish insulin compatibility with another presentation of the same insulin product.
- The pre-specified acceptance criteria include limits on insulin product quality attributes specific to the particular insulin product.

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.