510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K223846

B Applicant

Beta Bionics, Inc.

C Proprietary and Established Names

iLet® ACE Pump

D Regulatory Information

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

E Purpose for Submission:

New device

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.

The iLet System is only for use with insulin U-100 lispro (Humalog) or insulin U-100 aspart (Novolog).

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 ACE Pump is an alternate controller enabled (ACE) pump intended to automatically deliver insulin under the skin based on commands from an interoperable automated glycemic controller (iAGC) in people with diabetes mellitus. The iLet ACE Pump provides a graphical user interface and alerts to interact with the iLet delivery system and an iAGC.

The iLet ACE Pump includes a motor-drivetrain pumping mechanism, which actuates the delivery of insulin from a cartridge that is separately loaded into the iLet. The insulin is injected under the skin via continuous infusion.

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 should be changed every 3 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

t:slim X2 Insulin Pump with Interoperable Technology

B Predicate 510(k) Number(s):

K201214

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223846	K201214
Device Trade Name	iLet® ACE Pump	t:slim X2 insulin pump
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin at variable rates for the management of diabetes mellitus in people requiring insulin. Intended to be interoperable with connected devices including CGMs and automated insulin dosing algorithms	Same
Age Range of Intended Users	Ages 6 years and older	Same
Operating Environment	Home Use	Same
Specific Drug/Biologic Use	U-100 insulins: NovoLog and Humalog	Same
General Device Characteristic Differences		
Control Modes	iAGC closed-loop control only	iAGC closed-loop control, or open-loop manual control using basal and bolus delivery modes
Reservoir volume	1.6 mL	3.0 mL

V Standards/Guidance Documents Referenced:

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff

Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff

General Principles of Software Validation: Guidance for Industry and FDA Staff

Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff

Electromagnetic Compatibility (EMC) of Medical Devices, Guidance for Industry and Food and Drug Administration Staff

ANSI/AAMI ST72:2011 - Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing

ASTM D4169:2016 - Standard Practice for Performance Testing of Shipping Containers and Systems Performance Testing of Shipping Containers and Systems

ASTM F1140:2020 - Internal Pressurization Failure Resistance of Unrestrained Packages

ASTM F1980:2016 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM F2503:2013 - Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ASTM F88:2015 - Standard Test Method for Seal Strength of Flexible Barrier Materials

IEC 60601- 1:2005+AMD1:2012 Consolidated version - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1- 10:2008/A1:2013 - 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 60601-1-11:2015 - 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

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- 6:2010+A1:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-1- 8:2006/A1:2012 - 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 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices

IEC 62133-2:2017 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-2:2006 - Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-3:2014 - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

ISO 10993-4:2017 - Biological evaluation of medical devices - Part 4: Screening tests for blood to assess interactions

ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for cytotoxicity - In vitro methods

ISO 10993-6:2016 - Biological evaluation of medical devices - Part 6: Tests for evaluation of local effects after implantation

ISO 10993-10:2010/R 2014- Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-12:2021 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

ANSI AAMI ISO 11137- 1:2006/(R)2015 - Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

ISO 11607-1:2019 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11608-3:2012 - Needle-based injection systems for medical use - Requirements and test methods - Part 3: Finished containers

ANSI AAMI ISO 11737-1:2018 - Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product

ANSI AAMI ISO 11737-2:2019 - Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 14644-1:2015 - Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness

ISO 14971:2019 - Medical devices - Application of risk management to medical devices

EN ISO 15223-1:2016 - Medical devices - Symbols to be used with medical device labels, labelling and information supplied – Part 1: General requirements

ISO 80369-20:2015 - Small bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

EN ISO 80369-7:2021 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

ISO 8537:2016 - Sterile single-use syringes, with or without needle, for Insulin

ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices

ISO 11040-4 2015 - Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling

ISO 7000:2019 - Graphical symbols for use on equipment - Registered symbols

ISO/IEC 15459 – 2:2015 - Information technology - Automatic identification and data capture techniques - Unique identification - Part 2: Registration procedures

ISO/IEC 15459-4:2014 - Information technology - Automatic identification and data capture techniques - Unique identification - Part 4: Individual products and product packages

ISO/IEC 15459-6:2014 - Information technology - Automatic identification and data capture techniques - Unique identification - Part 6: Groupings (corrected 2016-09-01)

ISO/IEC 646:1991 - Information technology - ISO 7-bit coded character set for information interchange

UL 1642 - Standard for Lithium Batteries

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy, iLet ACE pumps were tested by delivering at minimum, intermediate, and maximum basal rates (0.1, 1.0, and 10.0 U/hr). A total of 30 devices (15 new and 15 aged) were tested at all basal rates. For both aged and unaged pumps, all cartridges were new. Water was used as a substitute for insulin. Water 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 (1a – 3b) report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rates settings for all pumps tested with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Table 1a: Amount of fluid delivered (by new pumps) after 1, 6, and 12 hours with 10 U/hr (maximum) basal rate setting

10 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**10 U**	**60 U**	**120 U**
Median amount delivered [min, max]	9.98 U [9.70, 10.36]	60.00 U [58.93, 60.67]	120.02 U [118.63, 121.01]

Table 1b: Amount of fluid delivered (by aged pumps) after 1, 6, and 12 hours with 10 U/hr (maximum) basal rate setting

10 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**10 U**	**60 U**	**120 U**
Median amount delivered [min, max]	9.98 U [9.69, 10.32]	59.90 U [59.07, 60.78]	119.81 U [118.62, 121.12]

Table 2a: Amount of fluid delivered (by new pumps) after 1, 6, and 12 hours with 1 U/hr (intermediate) basal rate setting

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered [min, max]	0.99 U [0.61, 1.37]	5.94 U [5.56, 6.35]	11.90 U [11.39, 12.33]

Table 2b: Amount of fluid delivered (by aged pumps) after 1, 6, and 12 hours with 1 U/hr (intermediate) basal rate setting

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered [min, max]	0.98 U [0.61, 1.33]	5.88 U [5.33, 6.28]	11.74 U [11.04, 12.31]

Table 3a: Amount of fluid delivered (by new pumps) after 1, 6, and 12 hours with 0.1 U/hr (minimum) basal rate setting

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 [min, max]	0.09 U [0.02, 0.12]	0.56 U [0.29, 0.65]	1.21 U [0.77, 1.25]

Table 3b: Amount of fluid delivered (by aged pumps) after 1, 6, and 12 hours with 0.1 U/hr (minimum) basal rate setting

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 [min, max]	0.09 U [0.02, 0.11]	0.55 U [0.33, 0.63]	1.11 U [0.79, 1.20]

2. Bolus Delivery Accuracy

To assess bolus delivery accuracy, 15 iLet devices were tested by delivering consecutive minimum, intermediate, and maximum bolus volumes (0.5, 5.0, and 30 units). All devices were new, and 15 additional devices were aged to simulate four years of regular use and tested by delivering consecutive intermediate bolus volumes. For both aged an unaged devices, all devices were tested with a new cartridge. Table 4 shows the number of total and consecutive boluses delivered in this testing for each delivery volume.

Table 4: Summary of bolus testing protocol

Bolus size (units)	Number of pumps tested	Consecutive boluses per pump	Total boluses
0.5 units	15	25	375
5.0 units	30	25	750
30 units	15	16	240

Water was used as a substitute for insulin. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy. Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. Tables 5 – 7 below show average, minimum, and maximum bolus sizes observed, as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

Table 5: Amount of fluid delivered after a 0.5 U bolus request

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 -	3/375 (1.1%)	13/375 (3.5%)	71/375 18.9%)	253/375 (67.5%)	29/375 (7.7%)	5/375 (1.3%)	0/375 -	0/375 -	0/375 -

Table 6a Amount of fluid delivered after a 5.0 U bolus request – New pumps

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 -	8/375 (2.1%)	362/375 (96.5%)	5/375 (1.3%)	0/375 -	0/375 -	0/375 -	0/375 -

Table 6b: Amount of fluid delivered after a 5.0 U bolus request – Aged pumps

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 -	1/375 (0.3%)	7/375 (1.9%)	366/375 (97.6%)	0/375 -	1/375 (0.3%)	0/375 -	0/375 -	0/375 -

Table 7: Amount of fluid delivered after a 30 U bolus request

Units delivered after a 25 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 for each delivery profile. To test the time between occlusion and pump alarm, pumps were physically occluded by closing the patient end of a connected infusion set after priming and either a 4 U bolus or a 0.1 or 1.0 U/hr basal rate was initiated. For each test, the time between occlusion and pump detection of occlusion was determined. 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. Results are presented in Table 8 below. After pumps alarmed, the occlusions were cleared, and the total amount of fluid delivered was measured. Typical volumes were 4 U.

Table 8: Delivery profiles used for occlusion detection testing

	Typical time to occlusion detection	Maximum time to occlusion detection
4.0 U Bolus	11 seconds	15 seconds
1.0 U/hr Basal	2 hours 51 minutes	3 hours 52 minutes
0.1 U/hr Basal	29 hours 29 minutes	39 hours 25 minutes

B. Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

As part of this submission, the sponsor provided a comprehensive hazard analysis, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors validation tests were conducted on the iLet System and described in more detail in the Decision Summary for K220916.

3. Biocompatibility

The iLet ACE pump was tested for biocompatibility in accordance with International Standard ISO-10993-1 as an external device with a permanent duration of patient contact. The biocompatibility information was reviewed and found to be acceptable.

4. Sterility

The iLet accessories (i.e., iLet Go Connect and iLet Go Cartridge underwent gamma sterilization validation in accordance with ISO 11137-1 and ISO 11137-2 using the VDMax method. The sterility information was reviewed and found to be acceptable.

5. Insulin Compatibility and Stability

The iLet ACE pump user-filled cartridge is compatible with U-100 insulins Novolog (insulin aspart) and Humalog (insulin lispro) for up to 3 days.

6. Additional Bench Testing

Additional verification testing that was conducted for the subject device is as follows:

Functional Testing
Water Ingress Testing
Drop Resistance Testing
Shock and Vibration Testing
Battery Single Charge Operational Life Testing
Battery Charge Time Testing
Low Battery Notification Testing
Cartridge Volume Testing
Cartridge Insertion Safety Testing
Prime Time Testing
Environmental Operation Testing
Alarm Pressure Level Testing
Operational Range Testing
Pump History Testing
Lead Screw Retraction Testing
Luer Lock Mechanical Integrity Testing
Fault Insertion Testing

7. Electromagnetic Compatibility and Wireless Coexistence

   Electromagnetic compatibility (EMC), electromagnetic immunity (EMI) and wireless coexistence testing was performed for the iLet ACE pump in compliance with IEC 60601-1-2 and RTCA DO-160G. The device passed all required testing with appropriate acceptance criteria and no deviations.

   Radiofrequency wireless testing was conducted, including wireless coexistence. Testing demonstrated that the device can operate in the presence of RF interference and co-exists with other wireless devices operating in the same vicinity. All tests passed.

8. Basic Safety and Essential Performance (Electrical Safety)

   The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalence for this device.

9. Data Logging

   Software verification testing has demonstrated the device records timestamped critical events, including information related to its state, user inputs, and device settings, as required by the special controls.

10. Interoperability

    A plan and approach for interoperability were provided according to the FDA Guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff" (issued on September 6, 2017) and found to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, the plans covered the sponsor's approach to working with third party manufacturers of digitally connected devices regarding contractual issues, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

    The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digitally interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be acceptable.

11. Software

    Detailed information on software of the device was reviewed and found to be acceptable.

12. Cybersecurity

    Detailed information on cybersecurity of the device was reviewed and found to be acceptable.

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.