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

Re: K231485
Trade/Device Name: iLet® ACE Pump
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: May 22, 2023
Received: May 23, 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 M. 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)*
K231485

Device Name
iLet® ACE Pump

Indications for Use *(Describe)*
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.

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) Summary
K231485:
Device Modification - iLet® ACE Pump
Prepared: June 16, 2023

Company: Beta Bionics, Inc.
300 Baker Avenue, Ste. 301, Concord, MA 01742
(978) 602-6239

Contact Person: Liz Cooper
Senior Regulatory Affairs Specialist
lcooper@betabionics.com
(732) 275-5848

Product Trade Name: iLet® ACE Pump

Common Name: Alternate controller enabled infusion pump (ACE pump)

Classification Name: Alternate controller enabled infusion pump

Regulation Number, Device Class and Pro Code: 21CFR 880.5730, Class II, QFG

Predicate Device: iLet® ACE Pump (Beta Bionics, Inc., K223846)

Purpose of Special 510(k) Notification:
The User Guide and Quick Reference Guide are being updated to indicate that the iLet bionic pancreas can be used with U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge.

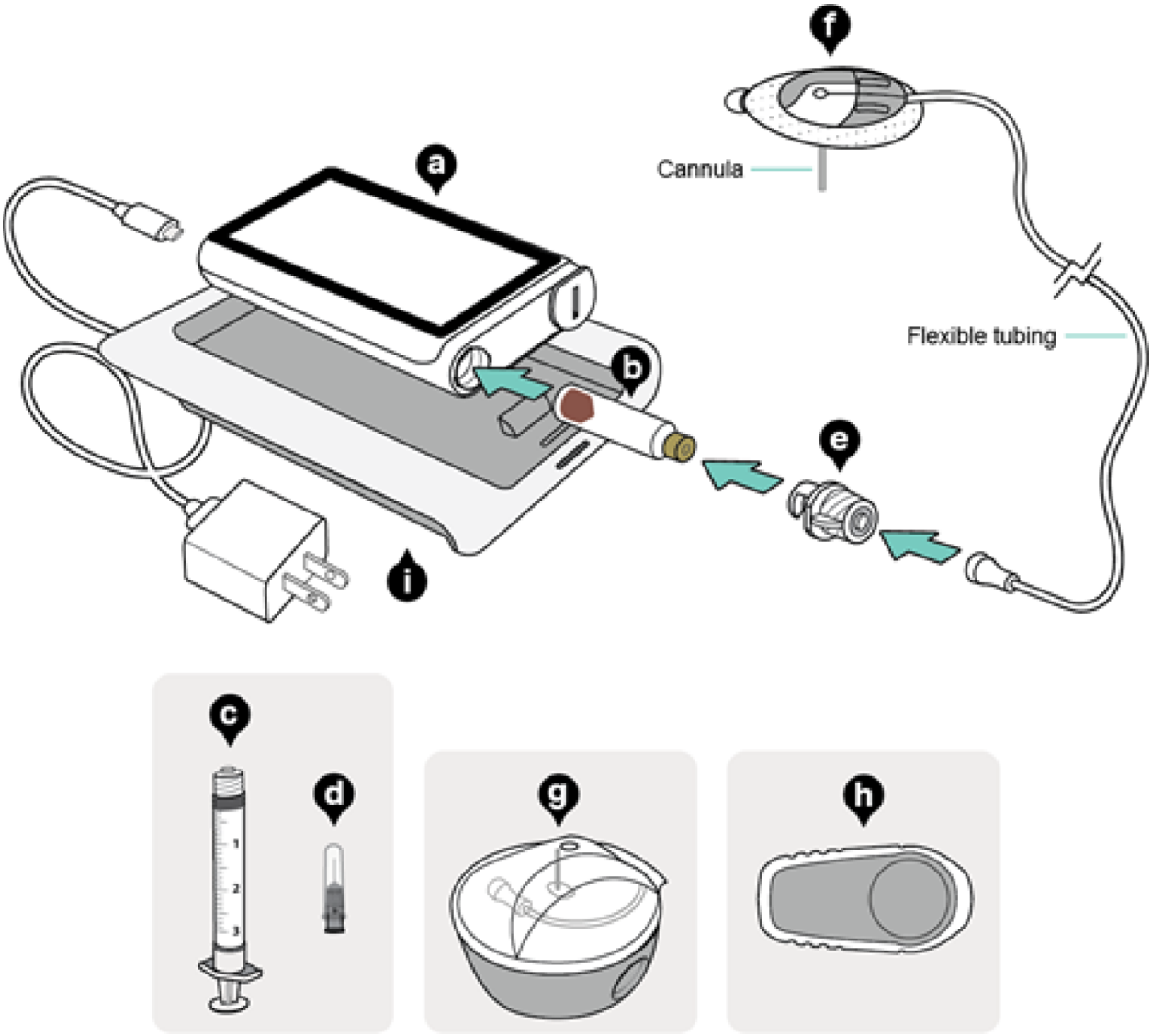
No significant changes have been made to the technological characteristics of the device.

Indications 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.

Device Description and Technological Characteristics:
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 provides a graphical user interface and alerts to interact with the iLet delivery system and an iAGC. The iLet Bionic Pancreas System is a collection of wearable medical devices that work together to deliver insulin with minimal user oversight. The iLet System is made up of the iLet bionic pancreas (consisting of the iLet ACE Pump (with accessories) and iAGC which resides on the ACE pump hardware), ACE pump disposables and accessories, iCGM and infusion set. The

insulin is filled for iLet use by a user, in a ready-to-fill cartridge (from an insulin vial supplied by a drug manufacturer) with the use of the syringe and needle. The iLet Bionic Pancreas System components are shown in Figure 1 below.

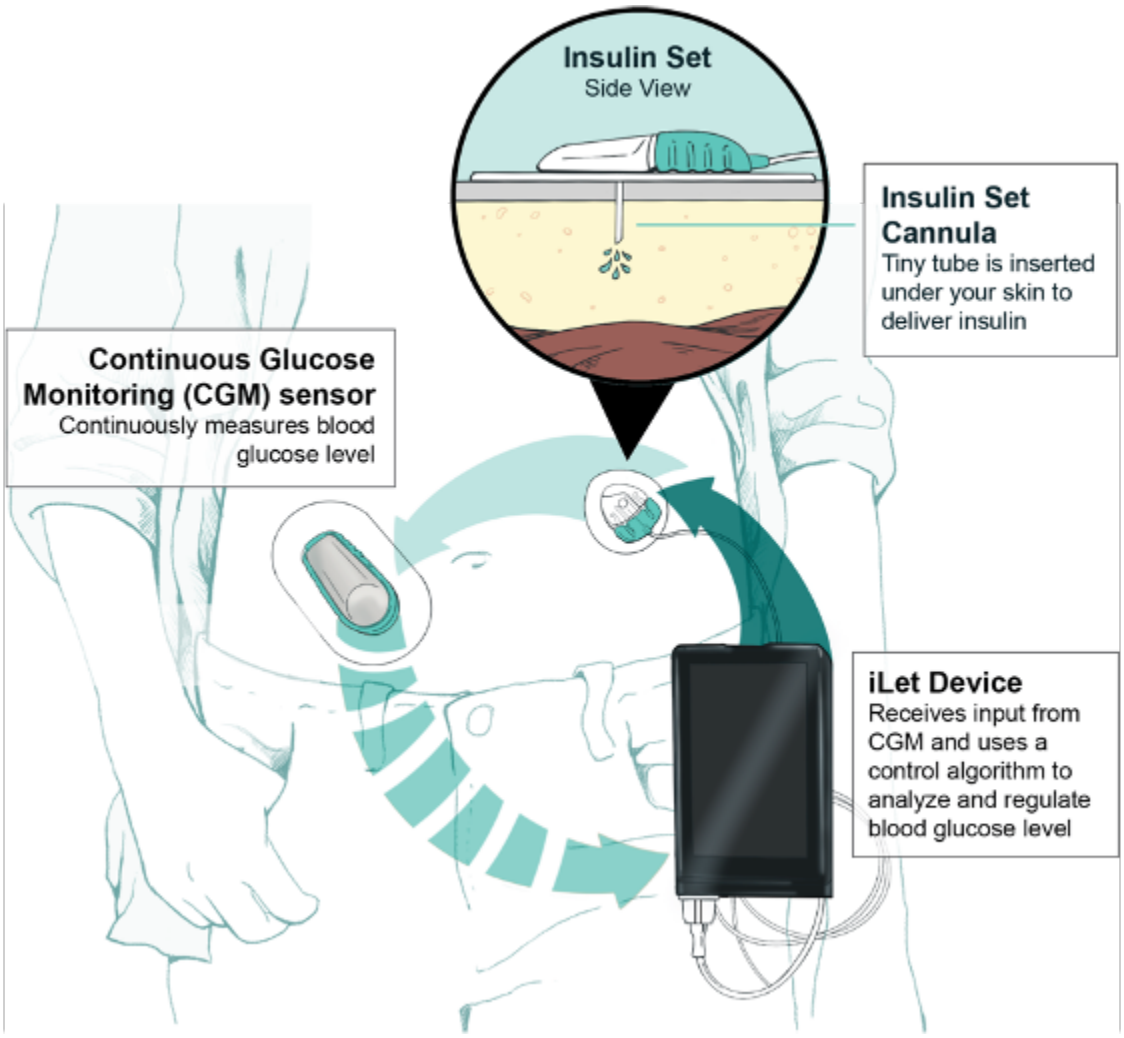
Figure 1: iLet Bionic Pancreas System



The iLet Bionic Pancreas System: (a) iLet ACE Pump; (b) iLet Cartridge (ready to fill cartridge); (c) Filling Syringe; (d) Needle; (e) iLet Connect (Luer connection adapter); (f) Infusion Set Base and infusion tube (g) Insulin Infusion Set, (h) iCGM (sensor and transmitter, example shown), and (i) iLet Charger (charging pad, micro-USB cable with power adapter)

For a better understanding of how the iLet bionic pancreas is used spatially on a person, it is shown applied to a human body in *Figure 2* below. The iCGM is shown communicating with the iLet via Bluetooth. The iLet ACE Pump gets glucose readings from the iCGM every 5 minutes and the iAGC uses that information as one of the inputs to calculate the person's insulin needs.

Figure 2: iLet Bionic Pancreas on a Person with Diabetes



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 figure above shows insulin being injected from the iLet through an infusion set. The infusion set must be placed at least 3 inches away from the iCGM sensor.

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. The insulin infusion set and iCGM sensor need to be changed as indicated in the manufacturers' labeling.

Table 1: Comparison of the Modified Device to the Cleared Device

Element of Comparison	iLet ACE Pump (Predicate Device) (K223846)	Subject Device
Intended Use	An ACE pump which is intended to work with an iCGM and iAGC to deliver insulin subcutaneously for the management of diabetes mellitus	Identical
Pump Type	Alternate controller enabled (ACE) infusion pump	Identical
Specific Drug / Biologic Use	U-100 Insulin System tested with NovoLog, Humalog	U-100 Insulin System tested with NovoLog, Humalog, and Fiasp
Prescription Status	Prescription Device	Identical
Size	9.10 cm L X 5.90 cm W X 1.50 cm H	Identical
Weight	110 grams (without infusion set)	Identical
Operating Conditions	Temperature: 41°F (5°C) to 104°F (40°C) Humidity: 15% to 90% RH non-condensing	Identical
Atmospheric Pressure	15.4 to 10.2 psia (Relative altitude -1300 feet to 10,000 feet)	Identical
Moisture Protection	IPX8: Protected against immersion in water for up to 12 feet for 30 minutes	Identical
Maximum Basal Rate	0 – 11.5 units/hr	Identical
Power Requirements	Rechargeable lithium battery powered device, wireless charging through a charging pad connected to a DC Adapter	Identical

Discussion of Non-Clinical Testing:
The same test methods previously established in K223846 for In-Use Stability, In-Use Compatibility, and Preservative Efficacy were followed, with acceptance criteria specific to Fiasp.

Discussion of Clinical Testing
No new clinical testing was required for this Special 510(k) notification. Clinical data to support use of Fiasp® (insulin aspart) with the iLet Dosing Decision Software was reviewed under K220916.

Conclusions
The modified device has been evaluated to be as safe and effective as the Predicate Device. Modifications to the device labeling do not raise any new or different questions of safety or effectiveness.