May 19, 2023

Beta Bionics, Inc.
Vikram Verma
Sr. Director, Regulatory Affairs
300 Baker Avenue, Suite 301
Concord, MA 01742

Re: K223846
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 5, 2023
Received: May 5, 2023

Dear Vikram Verma:

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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting Director
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)*
K223846

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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K223846 510(k) Summary

Manufacturer

510(k) Owner: Beta Bionics, Inc.
Address: 300 Baker Avenue, Ste. 301, Concord, MA 01742
Phone: (978) 602-6239

Contact Person

Name of Contact Person: Vikram Verma
E-mail: vverma@betabionics.com

Date of Summary Preparation: May 17, 2023

Device Names and Classification

Trade Name of Device: iLet® ACE Pump

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

Classification Name: Alternate controller enabled infusion pump (21 CFR 880.5730, QFG)

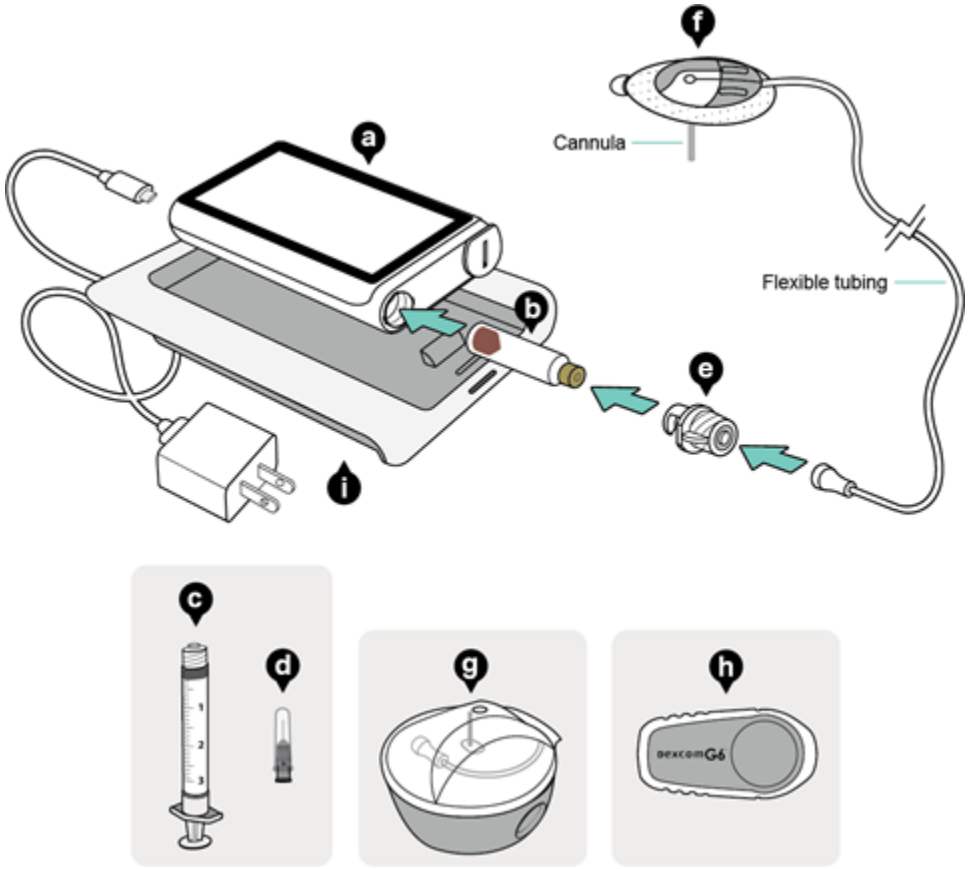
Predicate Devices
t:slim X2 insulin pump with interoperable technology (Tandem Diabetes Care, Inc., K201214)

Description of the iLet ACE Pump
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 may reside 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.

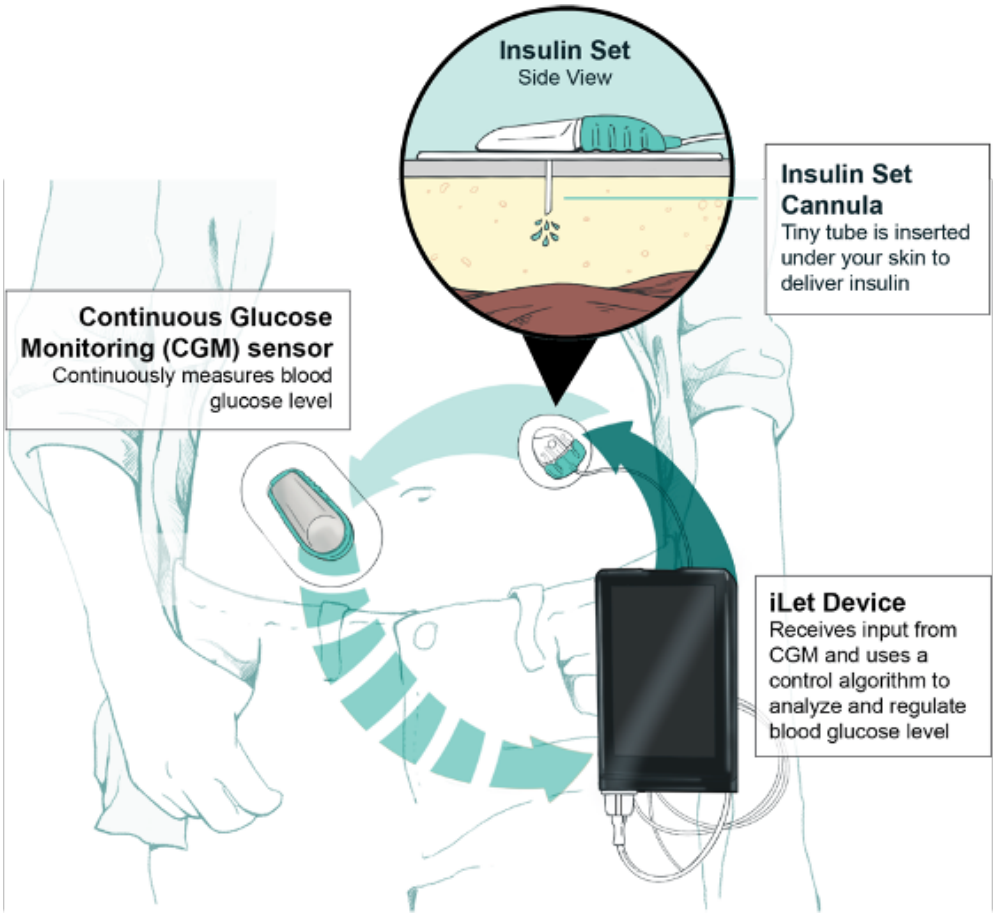
Figure 1: iLet Bionic Pancreas System



The iLet Bionic Pancreas System: (a) iLet ACE Pump; (b) iLet Cartridge (ready to fill cartridge); (c) Filling Syringe (Becton Dickinson); (d) Needle (Becton Dickinson); (e) iLet Connect (Luer connection adapter); (f) Infusion Set Base and infusion tube (Convatec) (g) Insulin Infusion Set (Convatec), (h) iCGM (Dexcom G6 sensor and transmitter), 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 (including tubing and base) needs to be changed every 2-3 days for infusion sets with a teflon cannula (Convatec Inset™ and Inset™ 30) and every 1-2 days for infusion sets with a steel cannula (Convatec Contact™ Detach) as indicated in the infusion set manufacturers' labeling. The iCGM sensor needs to be changed every 10 days.

Indications for Use for iLet ACE Pump

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.

Intended Use, Technological and Performance Characteristics of Subject Device Compared with Predicate Device

Table 1: iLet ACE Pump Comparison with Predicate Device

Element of Comparison	Tandem t:slim X2 Pump (Predicate Device) (K201214)	iLet ACE Pump (Subject Device)	Comment
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	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	Alternate controller enabled (ACE) infusion pump	Identical
Specific Drug / Biologic Use	U-100 Insulin Indicated for use with NovoLog or Humalog	U-100 Insulin System tested with NovoLog, Humalog	Similar
Prescription Status	Prescription Device	Prescription Device	Identical
Size	7.95 cm L x 5.08 cm W x 1.52 cm H	9.10 cm L X 5.90 cm W X 1.50 cm H	Similar
Weight	3.95 ounces (112 grams)	110 grams (without infusion set)	Similar
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing	Temperature: 41°F (5°C) to 104°F (40°C) Humidity: 15% to 90% RH non-condensing	Similar
Atmospheric Pressure	-1,300 feet to 10,000 feet (-396 meters to 3,048 meters)	15.4 to 10.2 psia (Relative altitude -1300 feet to 10,000 feet)	Identical
Moisture Protection	IPX7: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes	IPX8: Protected against immersion in water for up to 12 feet for 30 minutes	Similar
Maximum Basal Rate	15 units/hr.	0 – 11.5 units/hr	Basal rate in subject device is internal and cannot be set. Effective Rates are provided corresponding to isolated basal doses
Power Requirements	Rechargeable lithium battery powered device, USB-A wired charging through a DC Adapter	Rechargeable lithium battery powered device, wireless charging through a charging pad connected to a DC Adapter	Similar

Hazard Analysis, Risk Mitigation

A hazard analysis was conducted to account for the unique design elements, intended use, and risks of the iLet bionic pancreas. The hazard analysis accounted for the risks associated with interoperability between the device and other third-party digital devices which met predefined criteria but were not specifically identified, including scenarios in which the device was put into an environment in which both compatible and incompatible digital devices attempted to communicate with the device and deliver commands. 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.

In addition, a Use Related Risk Analysis (URRA) was conducted that identifies all User Groups, User Tasks, Possible Use Errors, Potential Clinical Harm to Patient, Severity of Harm, Risk Mitigations and Validation Methods associated with use of the iLet device. Critical tasks per the FDA's guidance document Applying Human Factors and Usability Engineering to Medical Devices 2016 are identified within the URRA. The URRA includes all warnings, cautions, and contraindications.

Summary of Non-Clinical Performance Data and Conclusions including compliance with Special Controls

Analytical Performance
The iLet ACE Pump was tested for dose delivery accuracy and occlusion detection. All tests passed.

Other Supportive Test Data

- Biocompatibility, Sterility, Insulin Compatibility and Stability, Electrical EMC and Safety, CGM connectivity, Packaging/ Shipping Integrity and Mechanical Tests:

  The iLet ACE Pump and accessories were subjected to the above tests as applicable. All tests passed.

- Data logging and Interoperability:

  The iLet ACE Pump has been validated for logging timestamped events, including information related to its state, user inputs, and device settings, as required by special controls. All tests passed.

  The iLet ACE Pump software has been validated to be interoperable with all connected devices.

- Cybersecurity:

  The iLet ACE Pump has incorporated adequate mitigations for cybersecurity risks. A cybersecurity analysis was performed using the draft FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Issued October 18, 2020, and the principles outlined in the FDA guidance, Postmarket Management of Cybersecurity in Medical Devices – Issued December 28, 2016. Beta Bionics has provided a software bill of materials and penetration testing.

- Labeling and Training:

  The iLet bionic pancreas device labeling and training for users and healthcare

practitioners was reviewed by the FDA. Labeling is sufficient and satisfies applicable requirements of 21 CFR 801 and 21 CFR 809.

Special Controls

The iLet bionic pancreas was found to be compliant with all Special Controls for Alternate controller enabled infusion pump (21 CFR 880.5730, QFG).

Summary of Human Factors and Clinical Performance Data and Conclusions

Human Factors

Beta Bionics executed a human factors and usability engineering process that followed and complied with FDA-recognized standards IEC62366:2015-1 and HE75:2009 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 iLet bionic pancreas (iLet ACE Pump with the iLet Dosing Decision Software installed) in a simulated use condition, including associated training and accompanying documentation. All critical tasks were tested in the validation study. The results of the validation study demonstrated the iLet system has been found to be safe and effective for the intended users for its intended uses in its intended use environment.

Clinical Performance

A clinical study was not required for the iLet ACE Pump as insulin delivery from the device can be verified through bench performance testing and use of the device was validated through a human factors validation study (described above).

Conclusions drawn from non-clinical tests that demonstrate safety, effectiveness, and performance to be as well as or better than predicate device

The preceding summary of predicate device comparison, non-clinical bench testing which supports the subject device design, and human factors study testing, demonstrate that the subject device performance in terms of safety and effectiveness is comparable to the predicate device.