



September 29, 2025

Beta Bionics, Inc.  
Liz Cooper  
Principal Regulatory Affairs Specialist  
300 Baker Ave, Suite 301  
Concord, Massachusetts 01742

Re: K252770

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: August 29, 2025  
Received: September 2, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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

## Indications for Use

510(k) Number (if known)

K252770

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 (CGM) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) K252770 Summary**  
**Device Modification - iLet® ACE Pump**  
Prepared: September 25, 2025

**Company:** Beta Bionics, Inc.  
300 Baker Avenue, Ste. 301,  
Concord, MA 01742

**Contact Person:** Liz Cooper  
Principal Regulatory Affairs Specialist

**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., K231485)

**Device Description:**

The iLet ACE Pump described herein includes changes to the graphic user interface (GUI) and alarms to improve the safety of the device. Instructions were added to the User Guide and Quick Reference Guide to advise users regarding CGM sensor calibration.

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

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 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, CGM 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 System consists of the iLet ACE Pump (K231485) with iLet Dosing Decision Software (K232224) and disposable consumables.

The iLet System is only for use with a compatible CGM and U-100 rapid acting insulin.

The CGM communicates with the iLet via Bluetooth. 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 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 CGM sensor need to be changed as indicated in the manufacturers’ labeling.

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

	<b>iLet ACE Pump (Predicate Device) (K231485)</b>	<b>iLet ACE Pump (Subject Device)</b>
<b>Intended Use</b>	An ACE pump which is intended to work with an CGM and iAGC to deliver insulin subcutaneously for the management of diabetes mellitus.	Identical
<b>Indications for Use</b>	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 is intended for single-person use; it is not to be shared.	Identical  The indications for use are unchanged for this submission.
<b>Pump Type</b>	Alternate controller enabled (ACE) infusion pump	Identical
<b>Specific Drug / Biologic Use</b>	U-100 Insulin System tested with NovoLog, Humalog, and Fiasp PumpCart®	Identical
<b>Prescription Status</b>	Prescription Device	Identical
<b>Size</b>	59 W X 91 L X 15 H millimeters	49 W X 91 L X 16 H millimeters
<b>Weight</b>	110 grams (without infusion set)	95 grams (without infusion set)
<b>LCD</b>	Monochromatic	Color
<b>Operating Conditions</b>	Temperature: 41°F (5°C) to 104°F (40°C) Humidity: 15% to 90% RH non-condensing	Identical
<b>Atmospheric Pressure</b>	15.4 to 10.2 psia (Relative altitude -1300 feet to 10,000 feet)	Identical
<b>Moisture Protection</b>	IPX8: Protected against immersion in water for up to 12 feet for 30 minutes	Identical
<b>Maximum Basal Rate</b>	0 – 11.5 units/hr	Identical
<b>Power Requirements</b>	Rechargeable lithium battery powered device, wireless charging through a charging pad connected to a DC Adapter	Identical

**Non-Clinical Testing and Compliance with Special Controls:**

- **Software Design Verification Testing:** Software verification testing was performed to verify that the changes to the graphic user interface (GUI) and alarms performed as expected and did not produce any unintended consequences. All tests passed.
- **Labeling:** The iLet ACE Pump labelling was reviewed by the FDA. Labelling is sufficient and satisfies applicable requirements of 21 CFR 801, 21 CFR 809, and 21 CFR 880.5730.
- **Special Controls:** The device meets all Special Controls for this product as required by 21 CFR 880.5730 for Alternate controller enabled infusion pumps, product code QFG.

**Clinical Performance:**

No new clinical testing was required for this Special 510(k) notification.

**Design Controls:**

The iLet ACE Pump was specified and developed by Beta Bionics. Beta Bionics complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as ISO 13485.

**Conclusions:**

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