April 30, 2026

Beta Bionics, Inc.
Douglas Ferguson
VP, Clinical and Regulatory
300 Baker Ave., Suite 301
Concord, Massachusetts 01742

Re: K253976
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: December 11, 2025
Received: December 12, 2025

Dear Douglas Ferguson:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253976

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) K253976 Summary
Device Modification - iLet® ACE Pump
April 30, 2026

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., K252770)

Device Description:
The iLet ACE Pump described herein includes a color LCD display and associated changes as well as a Pause Insulin feature. The User Guide and Quick Reference Guide are being updated to indicate that the iLet bionic pancreas can be used with U-100 insulin aspart (Fiasp). Labeling will be updated in accordance with the authorized PCCP to provide users with additional compatible insulin.

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 (K252770) 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 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 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

	iLet ACE Pump (Predicate Device) (K252770)	**iLet ACE Pump (Subject Device)**
Intended Use	An ACE pump which is intended to work with an CGM and iAGC to deliver insulin subcutaneously for the management of diabetes mellitus.	Identical
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.	Identical The indications for use are unchanged for this submission.
Pump Type	Alternate controller enabled (ACE) infusion pump	Identical
Specific Drug / Biologic Use	U-100 Insulin System tested with NovoLog, Humalog, and Fiasp PumpCart®	U-100 Insulin Similar Labeling will be updated in accordance with the authorized PCCP to provide users with additional compatible insulin.
Prescription Status	Prescription Device	Identical
Size	Monochromatic: 59 W X 91 L X 15 H millimeters	Color: 49 W X 91 L X 16 H millimeters
Weight	Monochromatic: 110 grams (without infusion set)	Color: 95 grams (without infusion set)
LCD	Monochromatic	Color
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

	iLet ACE Pump (Predicate Device) (K252770)	iLet ACE Pump (Subject Device)
Power Requirements	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:

- **Insulin Compatibility Testing:** Documentation supporting the use of U-100 insulin aspart (Fiasp) for ages 6 years and older is included in the submission.
- **Labeling:** The iLet ACE Pump labeling was reviewed by the FDA. Labeling 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.

Predetermined Change Control Plan

The predetermined change control plan (PCCP) for the device specifies anticipated modifications to the device insulin compatibility. The PCCP also specifies the methods to implement those modifications so that the device remains as safe and as effective as the predicate device. Upon completion of the validation activities described in the PCCP, the iLet labeling will be updated in accordance with the authorized PCCP to provide users with additional insulin compatibility.

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 and labeling do not raise any new or different questions of safety or effectiveness.