October 21, 2026

Beta Bionics, Inc.
Liz Cooper
Principal Regulatory Affairs Specialist
11 Hughes
Irvine, California 92618

Re: K263422
Trade/Device Name: Mint ACE Pump
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG
Dated: September 25, 2026
Received: September 25, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263422

Please provide the device trade name(s).

Mint ACE Pump

Please provide your Indications for Use below.

The Mint ACE Pump (Mint pump) is intended for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin. The Mint pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Mint ACE Pump is intended for the management of diabetes mellitus in people 6 years of age or older. The Mint pump is intended for single-person, home use and requires a prescription.

Please select the types of uses.

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☒ Children (2 years old to < 12 years old)
- ☒ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary

Manufacturer
510(k) Owner: Beta Bionics, Inc.
Address: 11 Hughes, Irvine, CA 92618
Phone: (855) 745-3800

Contact Person
Name of Contact Person: Liz Cooper (Principal Regulatory Affairs Specialist)
E-mail: lcooper@betabionics.com
Date of Summary Preparation: October 23, 2026

Device Names and Classification Trade Name of Device
Trade Name: Mint 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
Mint ACE Pump (Beta Bionics, 510(k) K260001)

Description of the Mint ACE Pump
The Mint ACE Pump described herein includes Mint Controller insertion and Mint Cartridge lockout improvements, new BLE module, and alarm logic modifications to reduce fatigue.

The Beta Bionics Mint System consists of the Mint pump (Mint ACE Pump preinstalled with iLet Dosing Decision Software), Mint cartridges, a continuous glucose monitor (CGM) and the Beta Bionics App.

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

Indications for Use: Mint ACE Pump
The Mint ACE Pump (Mint pump) is intended for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin. The Mint pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Mint ACE Pump is intended for the management of diabetes mellitus in people 6 years of age or older. The Mint pump is intended for single-person, home use and requires a prescription.

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

	Mint ACE Pump (Predicate Device) (K260001)	**Mint ACE Pump (Subject Device)**
Device Trade Name	Mint ACE Pump	Identical
510(k)	K260001	K263422
Manufacturer	Beta Bionics, Inc.	Identical
Product Code	QFG	Identical
Classification Regulation	Class II 21 CFR 880.570 – Alternate Controller Enabled Infusion Pump	Identical
Panel	CH – Clinical Chemistry	Identical
Intended Use/Indications for Use	The Mint ACE Pump (Mint pump) is intended for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin. The Mint pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software,	Identical The indications for use are unchanged for this submission.

	Mint ACE Pump (Predicate Device) (K260001)	Mint ACE Pump (Subject Device)
	to receive, execute, and confirm commands from these devices. The Mint ACE Pump is intended for the management of diabetes mellitus in people 6 years of age or older. The Mint pump is intended for single-person, home use and requires a prescription.	
Pump Type	Alternate controller enabled (ACE) infusion pump	Identical
Insulin Choice	U-100 rapid-acting insulin Novolog® and interchangeable biosimilar, KIRSTY	Identical
Prescription Status	Prescription Device	Identical
Operating Conditions	Temperature: 41°F to 104°F (5°C to 40°C) Humidity: 15 to 90%	Identical
Atmospheric Pressure	700hPA - 1060 hPA	Identical
Flow Rates and Profiles	Basal: 0.1 to 15 units/hour Bolus 0.1 to 30 units	Identical
Power Requirements	Disposable Batteries	Identical
Alarms and Alerts	Alarm Types: • Mint: Audible • Display: Visible, vibratory, audible (dependent on settings) Alarms: • Low Cartridge • Resume Insulin • Mint Software/Hardware Failure • Empty Cartridge • Occlusion Detected • Cartridge Expiration • Urgent Low Glucose • CGM Unavailable / Out of Range	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 alarms performed as expected and did not produce any unintended consequences. All tests passed.
- Labeling: The Mint 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 Mint 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 do not raise any new or different questions of safety or effectiveness.