



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K260001

B Applicant

Beta Bionics, Inc.

C Proprietary and Established Names

Mint ACE Pump

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	880.5730	Alternate controller enabled infusion pump	CH – Clinical Chemistry

E Purpose for Submission:

- New device
- Establish a Predetermined Change Control Plan (PCCP)

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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, 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.

C Special Conditions for Use Statement(s):

- Rx – For Prescription Use Only
- Always check your glucose frequently during amusement park rides and flying or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. Though the Mint System is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmospheric pressure in an airplane cabin can change during flight, which may affect the Mint pump's insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.
- Do not expose your Mint System to X-ray (screening at airports or other facilities and procedures), Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scan, diathermy treatment procedures, or to equipment used in procedures for Pacemaker / Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming, Cardiac Catheterization, or Nuclear Stress Test. Exposure of the Mint pump to any of these may damage it. Remove the Mint pump before undergoing these procedures.
- Do not use a Mint pump if you are sensitive to or have allergies to acrylic adhesives or have fragile or easily damaged skin. Applying a Mint pump under these circumstances could cause skin irritation, damage or infection.
- Remove your Mint System prior to any laser surgery as some lasers can create interference and cause your system to alert you.

III Device Description

The Mint ACE Pump (Mint pump) is a tubeless alternate controller enabled (ACE) Pump intended to automatically deliver insulin under the skin based on input from an integrated third party continuous glucose monitor (CGM) and an interoperable automated glycemic controller (iAGC) cleared under K262763 in people 6 years of age or older with diabetes mellitus.

The Mint is adhered to the user on the back of the arm, the lower back, the abdomen, the thigh area, or any site that has a layer of fatty tissue available. It is held in place by an adhesive pad and provides 3 days + 12-hour grace period of insulin delivery before insulin delivery is stopped automatically.

The Mint ACE pump consists of two components a controller and a cartridge: Mint Controller that is supplied non-sterile with a useful life of 2 years and interfaces with the iLet Dosing Decision Software that is pre-installed on the Mint controller. The Mint Controller collects glucose readings from a CGM every 5 minutes. The Mint cartridge is a disposable wearable component that is supplied sterile and can be filled with up to 200 Units of compatible U-100 rapid acting insulin. The Mint cartridge is intended to be used for a 3-day insulin delivery period plus a 12-hour grace period, after which insulin delivery stops automatically. The Mint pump is powered by a non-rechargeable battery in the disposable wearable component.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod 5 ACE Pump

B Predicate 510(k) Number(s):

K231826

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K260001</u>	<u>K231826</u>
Device Trade Name	Mint ACE Pump	Omnipod 5 ACE Pump
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin.	Same
General Device Characteristic Differences		
Intended patient population	For the management of diabetes mellitus in persons 6 years and older.	For the management of diabetes mellitus in persons 2 years and older.
Compatible insulins	U-100 rapid-acting insulin Novolog® and interchangeable biosimilar KIRSTY	U-100 rapid-acting insulin used for both basal and bolus doses: Novolog®, Humalog® and Admelog®
App host device	User's compatible mobile smartphone (Android or iPhone) with iLet App installed.	Omnipod 5 Locked Down Android Controller or user's compatible mobile smartphone (Android or iPhone) with Omnipod 5 App installed.

Flow Rates and Profiles	Basal: 0.1 to 15 units/hr Bolus 0.1 to 30 units	Basal: 0.05 - 30 units/hour Bolus: 0.05 - 30 units
Maximum Bolus Flow Rate	8 units per minute	1.5 units per minute

Predetermined Change Control Plan (PCCP):

In addition to the similarities and differences between the candidate and predicate devices, the candidate device has an authorized Predetermined Change Control Plan (PCCP) to allow for future modifications to the Mint ACE Pump. These modifications include addition of compatibility with U-100 Humalog (insulin lispro) and Fiasp (insulin aspart) insulins; and modification of the adhesive patch material, including the non-woven layer, skin-side adhesive, and device-side attachment method. Each modification is supported by a pre-specified Modification Protocol with defined acceptance criteria, including insulin compatibility testing (in-use stability, compatibility, and preservative efficacy against USP Monograph requirements) and adhesive patch bench testing (peel and bond retention forces) and biocompatibility testing (sensitization, irritation, and cytotoxicity per ISO 10993), with each modification released only after all predefined criteria are met. Upon successful completion, each modification will be implemented per Beta Bionics' QSR, including updates to labeling, risk management documentation, and Design History File (DHF), with ongoing monitoring through post-market surveillance.

V Standards/Guidance Documents Referenced:

- ISO 14971:2019 – Medical devices: Application of risk management to medical devices
- IEC 62304 Ed. 1.1 2015-06 – Medical device software: Software life cycle processes
- IEC 60601-1 Ed. 3.2 2020-08 – Medical electrical equipment: General requirements for basic safety
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD1:2021] – EMC Collateral Standard
- IEC 62366-1 Ed. 1.1 2020-06 – Application of usability engineering to medical devices
- ANSI AAMI ISO 10993-1:2018 – Biological evaluation of medical devices
- ISO 11607-1 and -2 Second Edition 2019-02 – Packaging for terminally sterilized medical devices
- ANSI AAMI ISO 11135:2014/A1:2018 – Sterilization: Ethylene oxide
- IEEE ANSI USEMCSC C63.27-2021 – Evaluation of Wireless Coexistence
- AAMI TIR69:2017/(R2020) – Risk management of RF wireless coexistence for medical devices
- ASTM D4169-22 – Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 – Accelerated Aging of Sterile Barrier Systems
- FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices (2016)

- FDA Guidance: Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions (2026)

VI Performance Characteristics:

A. Non-Clinical Performance

1. Basal Delivery Accuracy

To assess basal delivery accuracy, 29 Mint Pumps were tested by delivering at minimum, intermediate, and maximum basal rates (0.1, 1.0, and 10.0 units/hr). 14 of the 29 durable components for minimum, intermediate, and maximum basal had been aged to simulate two years of regular use. A combination of aged and unaged disposable cartridges was also used for this study. Water was used as a substitute for insulin.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warmup period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 0.1 U/hr (low) basal rate setting

0.1 U/hr Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	0.1 U	0.6 U	1.2 U
Median amount delivered	0.107 U	0.636 U	1.287 U
[min, max]	[0.000, 0.198]	[0.169, 0.914]	[0.492, 1.727]

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 1 U/hr (medium) basal rate setting

1 U/hr Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	1 U	6 U	12 U
Median amount delivered	0.996 U	5.978 U	11.958 U
[min, max]	[0.426, 1.274]	[5.450, 6.378]	[11.323, 12.579]

Table 3: Amount of fluid delivered after 1, 6 and 12 hours with 10 U/hr (high) basal rate setting

10 U/hr Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	10 U	60 U	120 U
Median amount delivered	9.888 U	59.418 U	118.841 U
[min, max]	[9.178, 10.215]	[58.462, 59.792]	[117.835, 119.173]

2. Bolus Delivery Accuracy

To assess bolus delivery accuracy, 29 Mint Pumps were tested by delivering consecutive minimum, intermediate, and maximum bolus volumes (0.1, 5.0, and 30 units). 14 of the 29

durable components for minimum, intermediate, and maximum bolus had been aged to simulate two years of regular use. Water was used as a substitute for insulin.

The number of total and consecutive boluses delivered in this testing for each delivery volume is described in Table 4 below:

Table 4: Summary of bolus testing protocol

Bolus size (units)	Number of pumps tested	Consecutive boluses per pump	Total boluses
0.1 units	29	100	2900
5 units	29	30	870
30 units	29	5	145

Table 5: Amount of fluid delivered after a 0.1 U bolus request

Units delivered after a 0.10 U bolus request (% of commanded units)								
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and percent of boluses	3/2900 (0.1%)	50/2900 (1.7%)	710/2900 (24.5%)	1435/ 2900 (49.5%)	655/2900 (22.6%)	45/2900 (1.6%)	2/2900 (0.1%)	0/2900 -

Table 6: Amount of fluid delivered after a 5.0 U bolus request

Units delivered after a 2.5 U bolus request (% of commanded units)								
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/870 -	0/870 -	16/870 (1.8%)	852/870 (97.9%)	2/870 (0.2%)	0/870 -	0/870 -	0/870 -

Table 7: Amount of fluid delivered after a 30.0 U bolus request

Units delivered after a 30.0 U bolus request (% of commanded units)								
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/145 -	0/145 -	0/145 -	145/145 (100%)	0/145 -	0/145 -	0/145 -	0/145 -

3. Occlusion Detection Accuracy

Occlusion detection testing was conducted on 30 Mint ACE Pump Systems. Testing included four conditions: 5 U bolus, minimum basal (0.1 U/hr), and intermediate basal (1 U/hr). Sixteen of the pumps used new disposables/durables, and the remaining combined aged conditions. Both aged and new disposables and durables were tested.

Table 8: Occlusion detection testing

	Typical time to occlusion detection	Maximum time to occlusion detection
≥ 5 U Bolus	19 seconds	29 seconds
0.1 U/hr Basal	35 hours 10 minutes	48 hours and 32 minutes
1 U/hr Basal	2 hours and 47 minutes	4 hours 38 minutes

B. Other Supportive Device Performance Characteristics Data

4. Additional Bench Testing

Reliability
Rapid pressure changes
Transient temperature changes
IPX8 submersion, drop, shock, vibration, impact
Chemical exposure
Shelf-life testing

5. Software and Cybersecurity

The software and cybersecurity documentation provided was determined to be adequate to support substantial equivalence.

6. Interoperability

A plan and approach for interoperability were provided for integration of CGM, iAGC and Mobile App and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices.

7. Biocompatibility

Biocompatibility testing was performed per FDA Guidance Document: Use of International Standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,” and FDA special controls for alternate controller enabled infusion pump. Results support a determination of substantial equivalence.

8. Sterility

The sponsor has performed adequate sterilization validation to demonstrate substantial equivalence.

9. Human Factors

Human Factors validation testing assessed users 6 years of age and older diagnosed with type 1 diabetes across multiple distinct user groups: adults with type 1 diabetes who independently manage their diabetes (including both pump users and MDI users); seniors (65 years and older) with dexterity or vision limitations; and pediatric patients (6–17 years), including both self-managing and caregiver-managed dyads, as well as newly diagnosed patients. The study included participants with varied experience levels, encompassing both AID-naïve and AID-experienced users. Training was standardized and consisted of either in-person or virtual sessions conducted by a certified in-person trainer.

10. Electronic Compatibility and Electrical Safety

Electromagnetic compatibility and electromagnetic immunity and wireless coexistence testing was performed for the pump. The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. All tests demonstrated that the device would perform as expected in the home healthcare environment.

11. Wireless Coexistence

Wireless coexistence was evaluated per ANSI/IEEE C63.27, as well as range and household coexistence protocols. Reports demonstrated robust BLE communication in coexistence, range, and household environments with no loss of safety or performance.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.