



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K234027

B Applicant

embecta Medical I, LLC

C Proprietary and Established Names

embecta Insulin Delivery System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Pump	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	CH - Clinical Chemistry

E Purpose for Submission:

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The embecta Insulin Delivery System (the Patch) with interoperable technology is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin, for individuals 18 years of age and older. The Patch 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 Patch is intended for single patient, home use and requires a prescription.

C Special Conditions for Use Statement(s):

This device is for prescription use only.

This device is intended for one-person use ONLY. Do not share the system with anyone – including other family members.

Insulin pump therapy is NOT recommended for people who are:

- Unable to monitor glucose levels as recommended by their health care provider.
- Unable to maintain contact with their health care provider.
- Unable to use the embecta Insulin Delivery System according to instructions.

Do Not adjust your Bolus Calculator or your Bolus Presets without the presence of your healthcare provider. Only your healthcare provider can help you change your Target and Minimum Glucose Level(s), Insulin-to-Carb Ratio, Insulin Sensitivity Factor, Duration of Insulin Action, and Bolus Presets. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

Before having an X-ray, magnetic resonance imaging (MRI), diathermy, electrocautery, or computed tomography (CT) scan (or any similar test or procedure), you'll need to disconnect and remove your patch. These types of tests and procedures can make your patch stop working. After your procedure is done, you can start over with a new patch.

The patch and controller are designed to use rapid-acting U-100 insulin. The following U-100 rapid acting insulin analogs have been tested and found to be safe for use in the pump: NovoLog or Humalog U-100 insulin for ages 18 years and older. NovoLog and Humalog are compatible with the system for use up to 72 hours (3 days). If you have questions about using other insulins, contact your health care provider. Always consult your health care provider and refer to the insulin labeling prior to use.

III Device Description

The embecta Insulin Delivery System is a prescription home use device intended to support insulin therapy for diabetes mellitus management. The pump is a disposable Insulin Delivery Device that is controlled by a Bluetooth Low Energy enabled Wireless Controller App housed on a locked down Android smartphone. In addition, the pump and controller will be packed with a syringe and needle for filling. The pump is a single use disposable sterile tubeless patch pump device intended to be worn by the patient for a nominal period of up to 72 hours. The pump is adhered to the patient using a medical grade adhesive patch and delivers insulin using a pump-gear mechanism. The body-worn pump stores and administers up to 300U of user-filled U-100 insulin with a selected basal and bolus dosage setting that is agreed upon between the user and their healthcare practitioner or provider. The U-100 insulin is delivered to the patient subcutaneously and both the pump and the controller app will send feedback on interrupted or

fault status to the patient. This will include successful activation and status changes such as calculation of a low or empty insulin reservoir volume, and pump failure (expiry/near expiry, hardware, software, communication failures, and occlusion).

The embecta-provided smartphone will be non-sterile and is locked to run only the embecta controller app that enables controlling the pump discreetly. The controller will enable the user to pair, prime, and program a basal and bolus dose via wireless transmission to the pump as well as provide users with system alerts, including status information and notifications. This includes, but is not limited to, battery life, total insulin delivered, calculation of a low insulin reservoir volume, occlusion, and other possible device faults. The controller's app is designed to program and display the patient's basal insulin delivery rate, delivered bolus doses, historical data, and insulin usage on a color display touch screen. The controller can be recharged with the provided charger.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod DASH Insulin Management System with Interoperable Technology

B Predicate 510(k) Number(s):

K191679

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K234027</u>	<u>K191679</u>
Device Trade Name	embecta Insulin Delivery System	Omnipod DASH Insulin Management System with Interoperable Technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin at variable rates for the management of diabetes mellitus in people requiring insulin. Intended to be interoperable with connected devices including CGMs and automated insulin	Same

	dosing algorithms.	
Operating Environment	Home Use	Same
Insulin Delivery Modes	Both basal and bolus	Same
Bolus Dose Range	0.05 – 30 U	0.05 – 30 U
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 Insulin. System has been tested with Novolog and Humalog.	U-100 Insulin. System has been tested with Novolog, Humalog, Admelog and Apidra.
Reservoir Capacity	300 U	200 U

V Standards/Guidance Documents Referenced:

- FDA Guidance “Infusion Pumps Total Product Life Cycle” dated December, 2014
- FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices” dated February, 2016
- FDA Guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, September, 2023
- FDA Guidance “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” dated September 6, 2017
- FDA Guidance “Content of Human Factors Information in Medical Device Marketing Submissions”, dated December, 2022
- ISO 10993-1:2018 Biological Evaluation of Medical Devices: Evaluation and Testing
- ISO 10993-3:2014 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-4:2017 Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity.
- ISO 10993-6: 2016 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation.
- ISO 10993-10:2021 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.

- ISO 10993-23:2021 Biological Evaluation of Medical Devices – Part 23: Tests for Irritation.
- ISO 14971 Third Edition 2019 Medical Devices – Application of Risk Management to Medical Devices
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances-Requirements and Tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8 Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- IEC 60601-1-11 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard- Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 62304:2015 Medical Device Software – Software Life Cycle Processes
- IEC 62366-1:2020 Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices
- ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- IEC 62366-1:2020 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices, including Amendment 1.

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy at 0.05, 1.0 and 30.0 U/h, 44 aged pumps and 45 unaged pumps were tested. Delivery accuracy was assessed by pumping insulin into a container on a scale and measuring the weight of the liquid at 1h, 6h, and 12h intervals for minimum and intermediate rates (0.1 and 1.0 U/hr) and 1h and 6h intervals for maximum rate (25 U/hr).

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum basal rate settings for all pumps tested.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 0.05 U/hr (minimum) basal rate setting

0.1 U/hr Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	0.05 U	0.30 U	0.60 U
Median amount delivered [min, max]	0.048 U [0.00, 0.18]	0.29 U [0.07, 0.45]	0.58 U [0.27, 0.72]

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

1 U/hr Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	1.0 U	6.0 U	12.0 U
Median amount delivered [min, max]	0.99 U [0.74, 1.20]	5.98 U [5.21, 6.14]	11.97 U [10.94, 12.26]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 30 U/hr (high) basal rate setting

25 U/hr Basal Duration	1 hour	6 hours
Total expected delivery volume	30 U	180 U
Median amount delivered [min, max]	30.13 U [29.77, 30.58]	180.49 U [180.10, 180.93]

2. Bolus delivery accuracy

To assess bolus delivery accuracy, a total of 90 pumps were used, half of which were aged. 30 pumps each were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.05 U, 6.0 U, and 30 U).

Tables 4-6 below show the number (and %) of boluses within the specified range of the minimum bolus, one intermediate bolus and the maximum bolus volume.

Table 4: Amount of fluid delivered after a 0.05 U bolus request (n=15000 boluses)

Units delivered after a 0.2 U bolus request (% of commanded units)										
	<0.0125 (<25%)	0.0125 - 0.0375 (25-75%)	0.0375- 0.045 (75-90%)	0.045- 0.0475 (90-95%)	0.0475- 0.0525 (95-105%)	0.0525- 0.055 (105-110%)	0.055- 0.0625 (110-125%)	0.0625- 0.0875 (125-175%)	0.0875- 0.125 (175-250%)	>0.125 (>250%)
Number and percent of boluses	5/15000 (0.03 %)	66/15000 (0.44 %)	1678/ 150000 (11.19 %)	4259/ 150000 (28.39 %)	7077/ 15000 (47.18 %)	1105/ 150000 (7.37 %)	792/ 15000 (5.28 %)	18/ 15000 (0.12 %)	0/150000 (0 %)	0/15000 (0 %)

Table 5: Amount of fluid delivered after a 6.0 U bolus request (n=750 boluses)

Units delivered after a 6.0 U bolus request (% of commanded units)										
	<1.50 (<25%)	1.50-4.50 (25-75%)	4.5-5.40 (75-90%)	5.40-5.70 (90-95%)	5.70-6.30 (95-105%)	6.30-6.60 (105-110%)	6.60-7.5 (110-125%)	7.5-10.5 (125-175%)	8.75-15.0 (175-250%)	>15.0 (>250%)
Number and percent of boluses	0/750 (0.0%)	0/750 (0.0%)	0/750 (0.0%)	1/750 (0.13%)	749/750 (99.87%)	0/750 (0.0%)	0/750 (0.0%)	0/750 (0.0%)	0/750 (0.0%)	0/750 (0.0%)

Table 6: Amount of fluid delivered after a 30 U bolus request (n=300 boluses)

Units delivered after a 30.0 U bolus request (% of commanded units)										
	<7.5 (<25%)	7.5-22.5 (25-75%)	22.5- 27.0 (75-90%)	27.0-28.5 (90-95%)	28.5-31.5 (95-105%)	31.5- 33.0 (105-110%)	33.0- 37.5 (110-125%)	37.5- 52.5 (125-175%)	52.5- 75.0 (175-250%)	>75.0 (>250%)
Number and percent of boluses	0/300 (0.0%)	0/300 (0.0%)	0/300 (0.0%)	0/300 (0.0%)	300/300 (100%)	0/300 (0.0%)	0/300 (0.0%)	0/300 (0.0%)	0/300 (0.0%)	0/300 (0.0%)

3. Occlusion detection

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 160 pumps were tested, half of which were aged.

The following table depicts the typical (average) time to occlusion detection for three different situations when using U-100 insulin.

Table 7: Timing of occlusion detection alarms

	Typical time to occlusion detection	Maximum time to occlusion detection
5.35 U Bolus*	2 minutes 15 seconds	3 minutes 34 seconds
1.0 U/hr Basal	4 hour 4 minutes	5 hours 27 minutes
0.05 U/hr Basal	79 hours 59 minutes	80 hours (Pump expiration)

*A 30 U bolus was commanded, and the reported value represents maximum amount of fluid at occlusion detection.

B. Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

A comprehensive hazard analysis was reviewed, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed. The sponsor performed a hazard analysis to account for the unique intended use, design elements, and risks of their ACE pump. 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.

2. Human Factors

The results of Human Factors (HF) validation study for the embecta Insulin Delivery System, a patch style insulin pump, support substantial equivalence to the predicate device. The HF validation study focused on two user groups: people with diabetes mellitus who are 18+ years or older and treated as adults and healthcare providers (HCP). The people with diabetes mellitus consisted of 16 “lay users,” where there were 6 pump-inexperienced, 6 pump-experienced, and 4 patients with caregivers represented as a dyad. The HCP group consisted of 15 certified diabetes care and education specialists and 1 clinical pharmacist. Users were trained according to a “train the trainer” model where trainers from embecta provided training to HCPs (registered nurses, diabetes educators, etc.) and the trained HCPs provided training to the people with diabetes. Lay-user training consisted of two one-on-one training sessions spread across two days. The first training focused on initial device set-up and basic

pump functionality and the second training focused on advanced pump functionality. There was a 1-hour decay period after training prior to validation testing. The tasks evaluated during simulated use testing consisted of administering a single rate basal program, manual boluses, adjusting time zones, temporary basal programs, multi-rate basal programs, bolus calculation based on carbohydrate and blood glucose values, pausing insulin delivery, alert customization, disposal of the device, and responding to alerts and alarms. Lay-users were not validated to set-up a new insulin pump independently and initial pump set-up, which consists of inputting pump settings such as setting up target glucose levels, preset boluses, insulin to carb ratio, insulin sensitivity factor, duration of insulin action, and minimum glucose level should occur under the supervision of a healthcare provider.

3. 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.

4. Sterility

The patch pump and filling syringe are provided sterile in a sealed sterile barrier tray. These components are terminally sterilized in its final package using Ethylene Oxide and the process has been validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11135: 2014.

5. Insulin Compatibility and Stability

The embecta system was found to be compatible with U-100 insulin Novolog (insulin aspart), and Humalog (insulin lispro) for up to 3 days.

6. Additional Bench Testing

In addition to the performance testing described above, mechanical testing, simulated use testing, and other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified. Summaries for reliability, safety, and verification testing follow:

Testing to Support System Reliability
Pump lifetime testing
Transient Temperature
Transient Pressure
Ingress Protection
Cleaning
Label legibility

Against mechanical stressors (e.g., vibrations, shock)
Against chemical stressors (e.g., sunscreens, insect repellents, chlorine and saltwater, cleaning agents)
Delivery Accuracy and Occlusion Detection Testing

Testing to Support System Safety
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Worst Case Accuracy
Incidental Delivery
Occlusion Detection Testing
Leakage
User Guide

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection
Insulin Delivery Verification
Environmental Conditions

7. Electromagnetic Compatibility and Wireless Coexistence

Electromagnetic compatibility, electromagnetic immunity and wireless coexistence testing was performed for the pump. All tests demonstrated that the device would perform as expected in the home healthcare environment.

8. Basic Safety and Essential Performance (Electrical Safety)

The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalent for this device.

9. Data Logging

The sponsor provided a summary of pump and controller logging capability which enable the device to record critical events including insulin delivery, pump commands and confirmations, connectivity states, malfunctions, and alarms. These were reviewed and found to be adequate.

10. Interoperability

A plan and approach for interoperability were provided according to the FDA Guidance *“Design Considerations and Pre-market Submission Recommendations for Interoperable*

Medical Devices” and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

11. Software and Cybersecurity

Detailed Information on software and cybersecurity of the device was reviewed and found acceptable.

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.