August 30, 2024

embecta Medical I, LLC
Andrew Harrell
Director, Regulatory Affairs, New Product Development
200 Bulfinch Drive, Suite 100
Andover, Massachusetts 01810

Re: K234027
Trade/Device Name: embecta Insulin Delivery System
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: July 22, 2024
Received: July 22, 2024

Dear Andrew Harrell:

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
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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)*
K234027

Device Name
embecta Insulin Delivery System

Indications for Use *(Describe)*
The embecta Insulin Delivery System with interoperable technology (the Patch) 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.

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) Summary**

**510(k):** **K234027**

**Submitted By**: Andrew Harrell
Director, Regulatory Affairs
embecta
200 Bulfinch Ave
Andover, MA 01810
Tel: 352-701-9489

**Date Prepared**: August 29, 2024

**Device Name:** embecta Insulin Delivery System
**Common Name:** Infusion pump
**Classification**: Class II device; 21 CFR 880.5730

**Product Code:** QFG (Alternate Controller Enabled Insulin Infusion Pump)

**Legally marketed predicate devices to which substantial equivalence is being claimed:**
K191679 – Omnipod DASH Insulin Management System with interoperable technology

**Device Description:**
The embecta Insulin Delivery System is a prescription home use device intended to support insulin therapy for diabetes mellitus (DM) management. The embecta Insulin Delivery System is a disposable insulin delivery device (referred to as a Patch) that is operated by a Controller which consists of Controller software application provided on a locked down smartphone with Bluetooth Low Energy (BLE) and Wi-Fi capabilities. See **Figure 1**.


**Figure 1.** embecta Insulin Delivery System Controller and Patch

The embecta Insulin Delivery System performs the following functions:

1) Deliver user-set daily basal insulin
2) Deliver user-set or user-entered mealtime (prandial) or correction insulin doses
3) Generate system status and notifications

***Insulin Delivery Device (Patch)***

The Patch is a single use disposable patch pump device intended to be worn by the patient for a Patch Life period of up to 72 hours (3 Days). The Patch is adhered to the patient using a medical grade adhesive patch. The Patch features a syringe pump design that operates dose increment

mechanism which controls the dose size. It stores and administers 300 U of user-filled U-100 insulin with variable basal and bolus dosage settings that are agreed upon between the user and their healthcare practitioner or provider. It is indicated for U-100 NovoLog® (insulin aspart) and U-100 Humalog® (insulin lispro).

***embecta Insulin Delivery System Controller App***

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

**Indications 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.

**Comparison with Predicate Devices:**

The overall intended use is the same as the predicate device, and the subject device indications for use statement differs from the predicate device as the subject device is indicated for adult use (18 years or older) and indicated for NovoLog® and Humalog® U-100 insulin.

The subject device has the same intended use as its predicate for the subcutaneous delivery of insulin. It also shares similarities in technology compared to its predicate device. These technological characteristics include the feature of an injection mechanism integrated into the delivery unit, basal and bolus delivery modes, battery operated, generation of system status and notifications, up to 72-hour wear, and a user filled reservoir. The subject device has a 300 U reservoir compared to the predicate device 200 U reservoir.

The subject device has a similar fundamental scientific technology as an electromechanical insulin delivery system as its predicate device. The main technological differences include larger reservoir, different basal settings, and needle insertion mechanism. Testing conducted supports substantial equivalence of the subject device despite these technological differences.

The table below provides a side-by-side comparison of the subject device compared to its predicate.

**Table 1: Predicate Device Comparison for embecta Insulin Delivery System**

| Feature | Subject Device: embecta Insulin Delivery System with interoperable technology | Predicate Device: Omnipod DASH Insulin Management System with interoperable technology | Comparison of Subject & Predicate Device |
|---|---|---|---|
| ***General*** | | | |
| *510(k) Number* | N/A | K191679 | N/A |
| *Classification* | II | II | Same |
| *Product Code* | QFG | QFG | Same |
| *Manufacturer* | embecta | Insulet Corporation | N/A |
| *Indications 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.<br><br>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. | The Omnipod DASH Insulin Management System (the Pump) 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. The 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 Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog®, Humalog®, Admelog®, or Apidra® U-100 insulin. | Same overall use, the subject device is indicated for adult patients and NovoLog® and Humalog® insulin only. |
| *Delivery Modes* | Basal and Bolus | Basal and Bolus | Same |
| *System Components* | • Electromechanical Pump<br>• Wireless Controller (WC) running on Smartphone | • Electromechanical Pump<br>• Wireless Controller (WC) running on Smartphone | Same |
| *Integration of Infusion Set* | Cannula integrated into pump (tubeless) | Cannula integrated into pump (tubeless) | Same |
| *Reservoir Capacity* | 300 U | 200 U | Larger reservoir capacity |
| *Insulin Concentration* | U-100 | U-100 | Same |
| *Microprocessor* | Yes | Yes | Same |
| *Power Source* | Battery Operated | Battery Operated | Same |
| *Programming Method* | Basal – WC<br><br>Bolus – WC | Basal – WC<br><br>Bolus – WC | Same |
| *System Notifications and Alarms* | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| *Cannula Material* | Integrated soft cannula | Integrated soft cannula | Same |
| *Replacement Frequency* | Disposable pump replaced every 72 hours | Disposable pump replaced every 72 hours | Same |
| *Provided Sterile* | Pump – Yes<br>WC - No | Pump – Yes<br>WC - No | Same |
| *Insulin Container* | Integrated patient filled container | Integrated patient filled container | Same |
| *Pump is packaged with filing syringe and needle* | Yes | Yes | Same |
| ***Basal Delivery*** | | | |
| *Number of Basal Rates* | Multiple and adjustable | Multiple and adjustable | Same |
| *Basal Programs* | 5 | 7 | Different |
| *Basal Rates per program* | Up to 6 | Up to 24 | Similar for equivalent coverages |
| *Basal Rate Range* | 0 – 30 U/hr<br>(0 – 720 U/day) | 0.05 – 30 U/hr<br>(1.2 – 720 U/day) | Similar |
| *Basal Rate Increments* | 0.05 U/hr | 0.05 U/hr | Same |
| *Basal Delivery Accuracy* | ±5% at rates ≥1U/hr<br>±15% at 0.05U/hr | ± 5% at rates ≥ 0.05 U/hr | Similar |
| *Temp Basal Duration* | 30 mins to 12 hours | 30 mins to 12 hours | Same |
| *Temp Basal Rate* | Flat rate 0-max basal rate 0 ± 95% | Flat rate 0-max basal rate (increments 0.05U) or 0 ± 95% | Similar |
| *Temp Basal Presets* | Up to 8 | Up to 7 | Different |
| ***Bolus Delivery*** | | | |
| *Bolus Dose Range* | 0.05 – 30 U | 0.05 – 30 U | Same |
| *Bolus Dose Increments* | 0.05, 0.1, 0.5, or 1.0 U | 0.05, 0.1, 0.5, or 1.0 U | Same |
| *Extended Bolus* | No | Yes | Different |
| *Bolus Dose Accuracy* | ± 5% for amounts ≥ 1.0 U<br>± 0.05 U for amounts < 1.0 U | ± 5% for amounts ≥ 1.0 U<br>± 0.05 U for amounts < 1.0 U | Same |
| *Bolus Dose Presets* | Up to 8 | Up to 7 | Different |
| ***Additional Features*** | | | |
| *Bolus Calculator* | Yes | Yes | Same |
| *Suspend Insulin* | Yes | Yes | Same |
| *Correction Factor* | Up to 6 time segments per day (1 to 400 mg/dL in 1 mg/dL) | Up to 8 time segments per day (1 to 400 mg/dL in 1 mg/dL) | Similar |
| *Insulin-to-Carb Ratio* | Up to 6 segments per day (1 to 150g carb/U) | Up to 8 segments per day (1 to 150g carb/U) | Similar |
| *WC History Storage* | At least 90 days of data | At least 90 days of data | Same |

**Summary of Non-Clinical Performance Data**

Risk Management:
Risk management was completed in accordance with ISO 14971: 2019. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met, and the device is safe for use.

Human Factors Validation:
embecta executed a human factors and usability engineering process which demonstrated the embecta Insulin Delivery System has been found to be safe and effective for the intended users, performing the expected tasks, in the expected use environments. It has been determined that the embecta Insulin Delivery System does not raise different questions of safety and effectiveness based on its technological characteristics. Evidence of this statement was collected through HF validation testing following focused usability activities consistent with FDA-recognized standards IEC 62366:2015-1 and HE75:2009 as well as the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices – Issued February 3, 2016.

Standards Compliance:

- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process - 2018 (5th Edition)
- ISO 10993-3 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity - 2014 (3rd Edition)
- ISO 10993-4 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood - 2017 (3rd Edition)
- ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity - 2009 (3rd Edition)
- ISO 10993-6 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation - 2016 (3rd Edition)
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (2nd Edition)
- ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization - 2021 (4th Edition)
- ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity - 2017 (3rd Edition)
- ISO 14971 Medical Devices – Application of risk management to medical devices - 2019 (3rd Edition)
- IEC 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- 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 - 2020 (4.1 Edition)]
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability - 2020 (3.2 Edition)
- 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 - 2020 (2.2 Edition)
- IEC 62304 Medical Device Software – Software Life-cycle processes - 2015 (1.1 Edition)

- IEC 62366-1 Medical Devices –Part 1: Application of usability engineering to medical devices, including Amendment 1 - 2020 (1.1 Edition)
- ANSI/AAMI ST72 Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing - 2019
- ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems - 2019 (2nd Edition)
- RTCA DO-160 Category R.
- IEC TR 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems – (1.0 Edition 2016-05)
- IEC 60601-2-24:2012 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
- 11607-2 Second edition 2019-02 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes
- ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices - Information to be supplied by the manufacturer
- IEEE Std 11073-40102:2020 Health informatics - Device interoperability. Part 40102: Foundational - Cybersecurity - Capabilities for mitigation.
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Analytical Performance:
The embecta Insulin Delivery System was tested for dose delivery accuracy and occlusion detection. All tests passed.

Accuracy and Occlusion Detection:

Accuracy for basal delivery, bolus delivery, and occlusion detection were evaluated and confirmed to be acceptable.

Basal Delivery:

To assess basal delivery accuracy, 89 embecta patch pumps were tested by delivering insulin at minimum, intermediate, and max basal rates (0.05, 1.00, and 30.0 U/hr). All 89 patch pumps were pre-conditioned for simulated shipping and handling, and 44 of which were treated by accelerated aging for simulated 6 month of shelf life. The following tables report the basal performance (median) observed, as well as the lowest and highest observed results for each of the basal rates, minimum, intermediate, and maximum for the pumps tested.

| **Low Basal Rate Delivery Performance (0.05 U/hr)** | | | |
|---|---|---|---|
| Basal Duration (Number of units requested | 1 hour (0.05 U) | 6 hours (0.30 U) | 12 hours (0.60 U) |
| Amount Delivered | 0.048 U | 0.29 U | 0.58 U |
| [min, max] | [0.00, 0.18] | [0.07, 0.45] | [0.27, 0.72] |

| Medium Basal Rate Delivery Performance (1.00 U/hr) | | | |
|---|---|---|---|
| Basal Duration (Number of units requested | 1 hour (1.00 U) | 6 hours (6.00 U) | 12 hours (12.00 U) |
| Amount Delivered | 0.99 U | 5.98 U | 11.97 U |
| [min, max] | [0.74, 1.20] | [5.21, 6.14] | [10.94, 12.26] |

| High Basal Rate Delivery Performance (30.00 U/hr) | | |
|---|---|---|
| Basal Duration (Number of units requested | 1 hour (30.00 U) | 6 hours (180.00 U) |
| Amount Delivered | 30.13 U | 180.49 U |
| [min, max] | [29.77, 30.58] | [180.10, 180.93] |

Note: A measurement at the 12-hour period with a 30.0 U/hr basal rate is not applicable to the system the reservoir will empty at approximately 10 hours at this rate.

Bolus Delivery:

To assess bolus delivery accuracy, 30 patch pumps were tested for each bolus size by delivering a minimum, intermediate, and maximum bolus amounts (0.05, 6.00, and 30.00 Units). All 90 pumps were pre-conditioned for simulated shipping and handling, and 45 of which were treated by accelerated aging for simulated 6 month of shelf life. For each bolus size represented in the tables below the number of boluses measured, as well as the number of boluses which were observed to be within the specified range of the target bolus volume, are provided.

| **Individual Bolus Accuracy Performance** | Target Bolus Size (Units) | Mean Bolus Size (Units) | Min Bolus Size (Units) | Max Bolus Size (Units) |
|---|---|---|---|---|
| Min Bolus Delivery Performance (n = 15000 boluses) | 0.05 U | 0.049 U | 0.001 U | 0.068 U |
| Intermediate Bolus Delivery Performance (n = 750 boluses) | 6.00 U | 5.99 U | 5.48 U | 6.14 U |
| Max Bolus Delivery Performance (n = 300 boluses) | 30.00 U | 30.09 U | 29.49 U | 30.63 U |

The tables below show for each requested bolus size, the range of amount of insulin that was observed delivered compared to the requested amount. Each table provides the number and percent of delivered bolus sizes observed within the specified range.

**Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request**

| **Amount (Units)** | <0.0125 | 0.0125-0.0375 | 0.0375-0.045 | 0.045-0.0475 | 0.0475-0.0525 | 0.0525-0.055 | 0.055-0.0625 | 0.0625-0.0875 | 0.0875-0.125 | >0.125 |
|---|---|---|---|---|---|---|---|---|---|---|
| **(% of target)** | (<25%) | (25-75%) | (75-90%) | (90-95%) | (95-105%) | (105-110%) | (110-125%) | (125-175%) | (175-250%) | (>250%) |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number and percent of boluses** | 5/15000 (0.03%) | 66/15000 (0.44%) | 1678/15000 (11.19%) | 4259/15000 (28.39%) | 7077/15000 (47.18%) | 1105/15000 (7.37%) | 792/15000 (5.28%) | 18/15000 (0.12%) | 0/15000 (0%) | 0/15000 (0%) |

**Amount of Insulin Delivery for an Intermediate (6.00 U) Bolus Request**

| **Amount (Units)** **(% of target)** | <1. 5 (<25%) | 1.5- 4.5 (25-75%) | 4.5-5.4 (75-90%) | 5.4-5.7 (90-95%) | 5.7- 6.3 (95-105%) | 6.3-6.6 (105-110%) | 6.6-7.5 (110-125%) | 7.5-10.5 (125-175%) | 10.5-15 (175-250%) | >15 (>250%) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number and percent of boluses** | 0/750 (0%) | 0/750 (0%) | 0/750 (0%) | 1/750 (0.13%) | 749/750 (99.87%) | 0/750 (0%) | 0/750 (0%) | 0/750 (0%) | 0/750 (0%) | 0/750 (0%) |

**Amount of Insulin Delivery for a Maximum (30.00 U) Bolus Request**

| **Amount (Units)** **(% of target)** | 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%) | 0/300 (0%) | 0/300 (0%) | 0/300 (0%) | 300/300 (100%) | 0/300 (0%) | 0/300 (0%) | 0/300 (0%) | 0/300 (0%) | 0/300 (0%) |

Occlusion (Blockage) Detection:

Occlusion detection testing was conducted using 160 pumps and 3 delivery profiles: >5.5U bolus, 1.0 U/hr basal rate, and 0.05 U/hr basal rate. All 160 pumps were pre-conditioned for simulated shipping and handling, and 80 of which were treated by accelerated aging for simulated 6 month of shelf life. Each pump was tested for the time between occlusion and pump alarm sequentially and for the 3 delivery profiles. All samples tested met performance that is presented in the table below.

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

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

Other Supportive Test Data:
Biocompatibility, Sterility, Insulin Compatibility and Stability, Electrical EMC and Safety, Packaging/ Shipping Integrity and Mechanical Tests were conducted. The embecta Insulin Delivery System and accessories were subjected to the above tests as applicable. All tests passed.

Data logging and Interoperability:
The embecta Insulin Delivery System has been validated for logging timestamped events, including information related to its state, user inputs, interoperability with qualified controllers and device settings, as required by special controls. All tests passed. The embecta Insulin Delivery System software has been validated to be interoperable with all qualified connected devices.

Cybersecurity:
The embecta Insulin Delivery System has incorporated adequate mitigations for cybersecurity risks. The embecta ACE Pump complies with Section 524B of the FD&C Act and follows FDA guidance on cybersecurity for medical devices. A robust cybersecurity risk assessment was conducted, and appropriate security controls and safeguards are in place to mitigate potential threats. A cybersecurity analysis was performed using the FDA guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September, 2023.

Labeling and Training:
The embecta Insulin Delivery System device labeling and training for users and healthcare practitioners was reviewed by the FDA. Labeling is sufficient and satisfies applicable requirements of 21 CFR 801 and 21 CFR 809.

Clinical Performance:
A clinical study was not required for the embecta Insulin Delivery System as insulin delivery from the device can be verified through bench performance testing and use of the device was validated through a human factors validation study (described above).

**Conclusions including compliance with Special Controls**

Special Controls: The embecta Insulin Delivery System was found to be compliant with all Special Controls for Alternate controller enabled infusion pump (21 CFR 880.5730, QFG).

Conclusions: The Subject Device serves the same functions of delivering insulin therapy that are the same as that of the Predicate Device. The required technical documentation provided in this Traditional 510(k) demonstrates the Subject Device is as safe and as effective as the Predicate Device. Therefore, the Subject Device has been evaluated to be substantially equivalent to the Predicate Device and does not raise new or different questions of safety or effectiveness.