



## 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

### I Background Information:

#### A 510(k) Number

K253534

#### B Applicant

Modular Medical

#### C Proprietary and Established Names

Pivot Insulin Delivery System

#### D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZG	Class II	21 CFR 880.5725	CH – Clinical Chemistry

#### E Purpose for Submission:

Modifications to predicate device

### II Intended Use/Indications for Use:

#### A Intended Use(s):

See Indications for Use below.

#### B Indication(s) for Use:

The Pivot Insulin Delivery System is indicated for the 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 greater.

#### C Special Conditions for Use Statement(s):

This device is for prescription use only.

This device is compatible with Humalog U-100 rapid-acting insulin only. Insulin Lispro (Generic Humalog) may be used in place of Humalog U-100 rapid acting insulin.

This device is contraindicated for:

- a) Diagnosing diabetes mellitus.
- b) Use by patients who do NOT have adequate hearing and/or vision to allow recognition of all functions of the Pivot System including Status and Alarms.
- c) Use by patients who cannot manage their Diabetes therapy.
- d) Use by patients unwilling to take a minimum of four (4) blood glucose readings per day.
- e) Use by patients who are unable to use the Pivot System in accordance with this User Guide.
- f) Use by patients who are not capable of following the User Guide.
- g) Use by patient populations requiring basal rates greater than 4 U/hr or less than 0.5 U/hr.
- h) Use with brands or concentrations of insulin other than Humalog U-100 insulin.

Do not expose your Pump within 6 inches from common products with magnets, including cell phone cases or wireless charging cases. Exposure to magnets or products with magnets may interfere with the Pump motor. Damage to the motor can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

Consistent drops of the Pump and/or exposure to personal care products such as lotions and sunscreens can result in significantly reduced Pump lifetime if also exposed to water. This may lead to severe hyperglycemia or Diabetic Ketoacidosis (DKA).

### **III Device Description**

The Pivot Insulin Delivery System is a modified version of the previously cleared MODD1 Insulin Delivery System (cleared under K240158) and consists of the following components: a reusable pump, a single-use insulin cartridge, a single-use integrated infusion set (patch) with built-in cannula for subcutaneous insulin delivery and adhesive pad for secure attachment to the patient's skin, a reusable inserter for cannula insertion, and the MMI App (smartphone application). The integrated infusion set component with built-in cannula and adhesive pad replaces the infusion set and adhesive pad components in the previously cleared MODD1 device. The insulin cartridge fluid path terminates in an exit port, which connects directly to the integrated infusion set for delivery of insulin through the cannula. Additional accessories to the Pivot System are FDA-cleared and include a single-use disposable syringe and needle (cleared under K821537 and K861153, respectively).

The Pivot System delivers insulin at basal rates between 0.5 and 4 units per hour (programmable in 0.1-unit increments) and user-selected bolus doses between 2 and 20 units (in 2-unit increments). Basal delivery may also be suspended for a set period of 30 minutes when required by the user.

Insulin delivery is achieved by gear motor rotation of a fixed-position camshaft that interfaces with the insulin cartridge pistons to control the movement of insulin from the cartridge reservoir into an interim chamber, through the exit port, and then through the cannula and into the patient's subcutaneous tissue. Software continuously monitors dispense output and generates alarms in the event of delivery issues (e.g., malfunctions, low reservoir volume, occlusions).

The MMI App is designed for use with iOS devices and allows configuration of a basal delivery schedule on the pump, supporting up to two basal rates in a 24-hour period. The MMI App and

pump communicate via Bluetooth Low Energy and near Field Communication. After the basal delivery schedule has been programmed on the pump, all insulin delivery functions are controlled through the pump user interface. Optional features of the MMI App include a dashboard display of current and historical pump information and delivery history.

Outside of user-initiated delivery requests such as bolus administration or basal suspension, once the basal schedule is configured the Pump operates autonomously. It continuously monitors delivery and provides audio-visual alarm signals as necessary until insulin delivery is interrupted due to depletion of the insulin reservoir, depletion of battery power, or expiration of the insulin cartridge (72 hours with an additional 8-hour grace period, for a total of 80 hours). At that point, the user replaces the insulin cartridge and infusion set and selects a new insertion site. The pump is reusable and can be operated for up to 90 days.

**IV Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Modular Medical MODD1 Insulin Delivery System

**B Predicate 510(k) Number(s):**

K240158

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K253534</u>	<u>K240158</u>
Device Trade Name	Modular Medical Pivot Insulin Delivery System	Modular Medical MODD1 Insulin Delivery System
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	The Pivot Insulin Delivery System is indicated for the 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 greater.	Same
Prescription or Over-the-Counter	Prescription use only	Same

Operating Environment	At home	Same
Compatible Drug	Humalog U-100 insulin	Same
Insulin Delivery Modes	Basal and Bolus	Same
Reservoir Volume	3 mL	Same
Use Time	Up to 72 hours	Same
<b>General Device Characteristic Differences</b>		
Components	Infusion Pump, Sterile disposable Insulin Cartridge (with direct exit-port interface), Sterile disposable Integrated Infusion Set (including cannula & adhesive pad), Reusable Inserter, MMI App (smartphone application)	Infusion Pump, Sterile disposable Insulin Cartridge, Disposable Adhesive Pad, Sterile disposable Infusion Set, MMI App (smartphone application)
Accessories	3 mL HSW HENKE-JECT® (Soft-Ject®) Luer Lock Syringe (K821537), EXEL International® 26G ½" Hypodermic Needle (K861153)	3 mL sterile syringe (K110771), 26-gauge sterile needle (K021475), Infusion Set Inserter (K163400)
Sterilization Method	Gamma sterilization	Gamma sterilization (Insulin cartridge) and ethylene oxide (infusion set)
Occlusion Alarm	<p>Bolus (4U or greater): 4 minutes and 46 seconds</p> <p>Intermediate Basal (2U/hr): 1 hour 45 minutes and 29 seconds</p> <p>Minimum Basal (0.5U/hr): 7 hours and 28 seconds</p>	<p>Bolus (2U or greater): 2 minutes 19 seconds</p> <p>Intermediate Basal (2U/hr): 31 minutes 31 seconds</p> <p>Minimum Basal (0.5U/hr): 2 hours</p>

## V Standards/Guidance Documents Referenced:

### Standards

- ISO 14971 Third Edition 2019-12, Medical Devices – Application of risk management to medical devices
- AAMI TIR101:2021, Fluid delivery performance testing for infusion pumps
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices – Part 1: Application of usability engineering to medical devices
- ANSI AAMI HE75:2009/(R)2018, Human factors engineering – Design of medical devices

### FDA Guidance Documents

- Infusion Pumps Total Product Life Cycle – Guidance for Industry and FDA Staff
- Use of International Standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (September 2023)

## VI Performance Characteristics:

### A. Analytical Performance

#### 1. Basal Accuracy

Basal accuracy is unchanged from the predicate device.

#### 2. Bolus Accuracy

Bolus accuracy is unchanged from the predicate device.

#### 3. Occlusion Detection

The time to detection of complete occlusions was measured. Pumps were physically occluded and after pumps alarmed, the occlusions were cleared and the total amount of fluid delivered was measured. The unintended bolus release after an occlusion is less than 3 U of insulin. The table below shows the typical time to occlusion detection under three different scenarios:

<b>Operating Rate</b>	<b>Typical</b>	<b>Maximum</b>
Bolus (4 U or greater)	4 minutes 41 seconds	4 minutes 46 seconds
Basal (2 U/h)	1 hour 45 minutes	1 hour 45 minutes
Basal (0.5 U/h)	7 hours 0 min	7 hours 0 min

### 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 infusion 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

Human Factors validation testing was conducted in the United States and validated the safe and effective use of the device with 16 people who had type 1 or type 2 diabetes aged 18 years or older and treated as an adult. There was a mix of insulin pump experience and naïve. Users had 4-57 years of diabetes management experience. The use of the system was validated only for users who can self-manage an insulin pump.

Users were provided 1:1 training by a trainer from Modular Medical that lasted up to 45 minutes and consisted of using the subject device with a trainer, using the quick start guide and the instructions for use, and reviewing the training slides. Training was conducted for only the subset use of the device (i.e., components, priming, and setup). Training consisted of walking users through how to use the system and instructional materials and users were allowed to complete the subset of steps required to use the device with assistance from the trainer and instructional materials as needed. At the end of training, users were required to demonstrate to the trainer how they would use the system. The trainer then made a final determination on a user being ready to use the subject device followed by a 1-hour decay period and subsequent Human Factors validation testing in a simulated home use environment.

Users were validated on their ability to use the subject device with the new insulin cartridge, infusion set, and inserter, as compared to the predicate device. Critical tasks associated with these design changes were identified based on the clinical harm severities that could occur due to use errors such as hypoglycemia, diabetic ketoacidosis, and infection.

## 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 results of the testing were found adequate.

## 4. Sterility

The insulin cartridge and integrated infusion set were sterilized with radiation and validated according to the ANSI/AAMI/ISO 11137 series and ANSI/AAMI/ISO 13004:2022.

## 5. Insulin Compatibility and Stability

Insulin compatibility studies were conducted on the subject device with Humalog U-100 insulin to demonstrate device material compatibility with the insulin, physicochemical stability of insulin when delivered through the device under simulated use conditions, and the continued ability of insulin to provide antimicrobial effectiveness after having been stored in the device. Compatibility study methods and results were found adequate to demonstrate substantial equivalence to the predicate device.

## 6. Additional Bench Testing

In addition to the performance testing described above, the subject device was subjected to additional testing to verify its reliability and to demonstrate that it can function over its intended use life (e.g., 90 days for the pump/controller, 80 hours for the infusion set, and 2 years for the inserter). This testing included cyclic reliability testing to simulate actual use of the pump including accelerated aging of insulin cartridges, simulation of packaging and shipping, insulin cartridges changes, and drops. Cyclic reliability testing for the reusable inserter included button presses, infusion set insertions, drops, and cleaning cycles to simulate 2 years of inserter use. Additional inserter testing demonstrated that the inserter attaches to the infusion set while the adhesive pad liner releases from the adhesive pad during removal from the packaging and safely deploys the cannula into simulated tissue without cannula damage. Functional testing included the ability of the pump to deliver insulin and detect occlusions. The reliability testing results supported that the device could function as intended for the intended duration, but that exposure to personal care products, drops, and subsequent exposure to water could impact pump survivability. The device labeling includes relevant warnings about such exposures and the associated risks.

## 7. Electromagnetic Compatibility and Wireless Coexistence

Electromagnetic compatibility, electromagnetic immunity and wireless coexistence testing was performed for the pump. The subject device meets immunity requirements per RTCA DO-160 (Susceptibility Category T). The subject device was also tested per FDA recognized standard IEC 60601-1-2:2020. All tests demonstrated that the device would perform as expected in the home healthcare environment.

## 8. Basic Safety and Essential Performance

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

## 9. Software and Cybersecurity

Detailed information on software was reviewed and found to be acceptable. The cybersecurity documentation supports that the device is cybersecure.

## **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.