



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K262153

B Applicant

Modular Medical Inc.

C Proprietary and Established Names

Pivot Insulin Delivery System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZG	II	21 CFR 880.5725 - Infusion Pump	CH - Clinical Chemistry

E Purpose for Submission:

Modifications to the Pivot Insulin Delivery System cleared under K253534.

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):

Rx – For prescription use only.

The Pivot System is contraindicated for:

- a. 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
- b. Use by patients who cannot manage their Diabetes therapy
- c. Use by patients unwilling to take a minimum of four (4) blood glucose readings per day
- d. Use by patients who are unable to use the Pivot System in accordance with this User Guide
- e. Use by patients who are not capable of following the User Guide
- f. Use by patient populations requiring basal rates greater than 4 U/hr or less than 0.5 U/hr
- g. 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).

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pivot System specified by the manufacturer. This could cause disruptions in device performance or a device malfunction, which may lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

Do not expose the Pump to unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy devices. Exposure to these devices can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

Do not expose your Pivot System to X-ray screening used for carry-on and checked luggage. Newer full-body scanners used in airport security screening are also a form of X-ray screening and your Pivot System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your Pivot System cannot be exposed to X-ray machines and request an alternate means of screening.

The Pivot System is incompatible with certain common products that are used on the skin. These include bug sprays with or without DEET, perfumes, deodorant sprays, body lotions and sunscreens. Use of these products on the Pivot System itself or where the System is adhered to the skin can cause cracks in the plastic used to manufacture the Pivot components. DO NOT allow these products to come in contact with the Pump, Cartridge or Inserter. ALWAYS remove your Pump before applying these products and ALWAYS wash your hands before handling your Pump, Cartridge or Inserter after using such products. ALWAYS change your Cartridge if it becomes exposed to such products and immediately clean your Pump. Failure to do so may result in damage to the Pump, Insulin Cartridge or Inserter and in some cases lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA).

Do not use Pivot System components if they have been dropped as there could be unseen damage to the device that could lead to moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

Do not use the System in oxygen-rich environments, environments rich in flammable anesthetics, or other volatile agents as this presents a risk of fire or explosion that could lead to injury.

III Device Description

The Pivot Insulin Delivery System is a software-controlled, programmable insulin infusion pump intended for the subcutaneous delivery of insulin for the management of diabetes mellitus. The system consists of a reusable Pump, a disposable Insulin Cartridge containing an integrated battery, a disposable Integrated Infusion Set with a built-in cannula for subcutaneous insulin delivery, a reusable Pivot Inserter for cannula insertion, an adhesive pad for secure attachment to the patient's skin, and the Pivot Diabetes App.

The Pump delivers insulin using a microprocessor-controlled, gear-motor-driven mechanism that transfers insulin from the Insulin Cartridge through the Integrated Infusion Set for subcutaneous infusion. The Pump provides programmed basal insulin delivery and user-initiated bolus insulin delivery. Insulin delivery is continuously monitored by system software, which provides alarms and notifications for conditions such as delivery interruptions, occlusions, low reservoir volume, and other system conditions.

The Pivot Diabetes App is used for system setup, configuration of therapy settings, review of system status, alarm information, and insulin delivery history.

The system delivers insulin at programmable basal rates between 0.5 and 4.0 units per hour in 0.1-unit increments. User-selectable bolus increment settings allow bolus doses to be delivered in predefined increments. Individual bolus deliveries are limited to a maximum of 20 units. Basal insulin delivery may be temporarily suspended by the user for up to two hours and resumed at any time during the suspension period.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Pivot Insulin Delivery System

B Predicate 510(k) Number(s):

K253534

C Comparison with Predicate(s):

Device & Predicate Device(s):	K262153	K253534
Device Trade Name	Pivot Insulin Delivery System	Same
General Device Characteristic Similarities		

Intended Use/Indications For Use	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
General Device Characteristic Differences		
Priming initiation timeout, minutes	45	30
Quick Bolus	Max 20U or ≤ 10 button presses at configured bolus increment of 0.5, 1, 2, 3, or 4U	Min 2U and max 20U with fixed increment of 2U per button press
Basal delivery suspension	2 hours, but can be resumed at any time using the Pump Control Button	Fixed 30 minutes
Resumable alarms	Yes	No
How to address alarms is on the app	Yes	No
Cartridge and infusion set package configuration	5-pack	10-pack

V Standards/Guidance Documents Referenced:

- ANSI AAMI ISO 11137-1:2006/(R)2015, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
- ISO 11137-2 Third edition 2013-06 [Including AMD1:2022], Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]
- ISO 11137-3 Second edition 2017-06, Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- ISO 11737-2 Third edition 2019-12, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ANSI AAMI ST72:2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
- ASTM D4332-22, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ISO TS 21726 First edition 2019-02, Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
- ASTM D7386-16, Standard Practice for Performance Testing of Packages for Single Delivery Systems

- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F2096-11 (Reapproved 2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 11607-1 Second edition 2019-02 [Including AMD1:2023], Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]
- USP-NF M98900_01_01, <151> Pyrogen Test (USP Rabbit Test)
- USP-NF M98830_02_01, <85> Bacterial Endotoxins Test
- USP-NF M98910_01_01, <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests
- 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
- ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- IEC TR 80002-1 Edition 1.0 2009-09, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software
- ANSI AAMI SW91:2018, Classification of defects in health software

VI Performance Characteristics:

A. Non-Clinical Performance

1. Basal Accuracy

Basal accuracy is unchanged from the predicate device.

2. Bolus Delivery Accuracy

Bolus accuracy at intermediate and maximum bolus sizes (i.e., 10 and 20 U) is unchanged from the predicate device.

To assess bolus delivery accuracy of the new programable minimum bolus size of 0.5 U, 20 pumps (10 new and 10 aged) were tested by delivering the minimum bolus amount (0.5 U). The actual bolus volume delivered was compared to the expected bolus volume. The tables below show the number (and %) of boluses within the specified range of each target bolus volume for the new and the aged pumps separately.

Table 1: Amount of fluid delivered after a 0.5 U bolus request, 298 boluses, 10 new pumps

Units delivered after a 0.5 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%

Units delivered after a 0.5 U bolus request (% of commanded units)										
Number and percent of boluses	0/298 -	0/298 -	29/298 (9.7%)	53/298 (17.8%)	200/298 (67.1%)	16/298 (5.4%)	0/298 -	0/298 -	0/298 -	0/298 -

Table 2: Amount of fluid delivered after a 0.5 U bolus request, 297 boluses, 10 aged pumps

Units delivered after a 0.5 U bolus request (% of commanded units)										
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and percent of boluses	0/297 -	0/297 -	31/297 (10.4%)	72/297 (24.2%)	191/297 (64.3%)	3/297 (1.0%)	0/297 -	0/297 -	0/297 -	0/297 -

3. Occlusion Detection

Occlusion detection is unchanged from the predicate device.

B. Clinical Studies:

NA

C. Other Supportive Device Performance Characteristics Data

4. Additional Bench Testing

In addition to the performance testing described above, other device verification testing was conducted, including:

- Battery performance testing was conducted to verify that changes made to battery connection, piezo and new motor do not negatively impact battery performance. 29 finished goods with build and sterilization records were able to operate beyond the acceptance criteria 80 hours + 3 minutes.
- Reliability verification was conducted using 29 devices to verify that the design changes to battery connection, piezo and new motor do not have an impact on the performance, durability, and robustness of the Pivot Insulin Delivery System after simulated shipping and handling, repeated insulin cartridge connection and disconnection, and drops.
- Software testing was conducted to verify that the software meets the performance requirements in monitoring the essential performance of the pump, that the controller software will trigger and log the designed alarms, and that the software meets controller states, state transitions, and logging requirements.

5. Sterility

The provided information about sterility is acceptable.

6. Human Factors

Human Factors validation testing was conducted in the United States and assessed use of the modified device with 16 people diagnosed with either type 1 or type 2 diabetes aged 18 years or older. Use tasks associated with the new features of the modified device were evaluated. Critical tasks associated with these design changes were identified based on the clinical harm severities that could occur due to use errors. K253534 HF data are leveraged for unchanged tasks.

7. Software

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

8. Leveraged Information from the predicate device cleared under K253534

- a. Biocompatibility and drug compatibility are not impacted by the proposed changes in this submission.
- b. Cybersecurity is unaffected by the changes proposed in this submission.
- c. Interoperability is unchanged.
- d. Wireless coexistence is unchanged from the predicate device.
- e. IEC 60601-1 and its collateral standards including EMC were leveraged from the predicate device.

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.