April 8, 2026

Modular Medical
Kelsie DiPerna
Sr. Regulatory Affairs Specialist
10740 Thornmint Road
San Diego, CA 92127

Re: K253534
Trade/Device Name: Pivot Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LZG
Dated: October 10, 2025
Received: November 18, 2025

Dear Kelsie DiPerna:

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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 and
Toxicology Devices
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)*
K253534

Device Name
Pivot Insulin Delivery System

Indications for Use *(Describe)*
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.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Table 1: Submitter and Device Information

Submitter Name	Modular Medical, Inc.
Submitter Address	10740 Thornmint Road San Diego, CA 92127
Contact Person	Kelsie DiPerna Senior Regulatory Affairs Specialist (808) 315-6427 kelsie@modular-medical.com
Device Trade / Proprietary Name	Pivot Insulin Delivery System
Device Common Name	Pump, Infusion, Insulin
Regulation Medical Specialty	General Hospital
Review Panel	Clinical Chemistry
Product Code	LZG (Class II) - Pump, Infusion, Insulin
Regulation	21 CFR 880.5725 - Infusion pump
Submission Type	Traditional 510(k)
Predicate Device	Modular Medical MODD1 Insulin Delivery System (K240158)
Date Prepared	March 12, 2026

1.0 Purpose of Submission

The Pivot Insulin Delivery System is submitted as a Traditional 510(k) premarket notification. The subject device is a modification of the legally marketed MODD1 Insulin Delivery System (K240158), rebranded as the Pivot Insulin Delivery System. The Indications for Use remain identical between the subject and predicate device.

The modifications include:

- A new Integrated Infusion Set component to replace the separate Infusion Set and Adhesive Pad components of the predicate device;
- Addition of a reusable Pivot Inserter for deployment of the Integrated Infusion Set, replacing the external Orbit Inserter accessory supplied with the predicate device;
- Revised Insulin Cartridge connection interface for direct coupling with the Integrated Infusion Set; and
- Updated packaging configurations supporting these changes.

Verification and validation testing, including biocompatibility, sterility, and bench testing, were conducted to support the substantial equivalence of the subject device. This testing demonstrates that these modifications do not alter the fundamental scientific technology or intended use, and do not raise different questions of safety or effectiveness.

2.0 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.

3.0 Device Description

The Pivot Insulin Delivery System (i.e., "Pivot System") is a second-generation configuration of the cleared MODD1 Insulin Delivery System (K240158), the predicate device for this submission. The Pivot System maintains the same fundamental operating principle and intended use as the predicate device, subcutaneous delivery of insulin at programmed basal and bolus rates for the management of diabetes mellitus—but introduces updates to improve usability and simplify the user interface through integration of components.

The Pivot System consists of the following:

- A reusable, software-controlled programmable Pump that delivers insulin through a microprocessor-controlled, gear-motor-driven multi-piston mechanism identical to that of the predicate device;

- A single-use, disposable 3.0mL (300 unit) Insulin Cartridge with an integrated battery to supply power to the Pump and direct-connect interface to the Integrated Infusion Set;
- A single-use, disposable Integrated Infusion Set with a built-in cannula for subcutaneous insulin delivery and adhesive pad for secure attachment to the patient's skin;
- A reusable Pivot Inserter, designed to insert the Integrated Infusion Set subcutaneously in a controlled, consistent manner; and
- The Pivot Diabetes App, a smartphone application used to configure and transmit the basal delivery schedule to the Pump.

Accessories to the Pivot System are FDA-cleared and include a single-use disposable syringe (K821537) and needle (K861153) used to fill the Insulin Cartridge reservoir.

The Pivot System is compatible with Humalog U-100.

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

Insulin delivery is achieved by gear-motor rotation of a fixed-position camshaft within the Pump that drives the pistons of the Insulin Cartridge to transfer insulin through the internal fluid path to the cannula of the Integrated Infusion Set. Software monitors dispense output using redundant sensors and provides alarms for conditions such as malfunctions, occlusions, or low reservoir volume.

The Pump and Pivot Diabetes App components of the Pivot Insulin Delivery System retain the same fundamental design and medical device functions as the MODD1 System.

4.0 Summary of Technological Characteristics Compared to Predicate Device

The Pivot Insulin Delivery System has the same fundamental technological characteristics as its predicate, the Modular Medical MODD1 Insulin Delivery System (K240158). Both are motor-driven, software-controlled, programmable insulin infusion pumps designed for subcutaneous delivery of insulin at set and variable basal and bolus rates.

The subject device retains the identical operating principle, control logic, and intended use as the predicate. The technological differences are limited to the integration of the infusion set components, the introduction of the reusable inserter, and the associated interface changes.

Non-clinical performance data, including biocompatibility, sterility, and human factors testing, demonstrate that these modifications do not raise different questions of safety or effectiveness. The Pivot System is substantially equivalent to the predicate device.

5.0 Performance Data

Verification and qualification testing were performed based on an evaluation of risks associated with the design modifications to the MODD1 Insulin Delivery System. All changes—including the new Integrated Infusion Set component, addition of the reusable Inserter, modified Insulin Cartridge, and packaging updates—were assessed to ensure that all potential risks were mitigated (e.g., insulin delivery accuracy, occlusion detection, adhesive strength, sterilization effectiveness, and biocompatibility). Testing confirmed that no new risks were introduced as a result of these modifications. Completed testing to support the determination of substantial equivalence included:

- Biocompatibility Testing
- Insulin Compatibility and Stability Testing
- Antimicrobial Effectiveness Testing
- Sterilization Validation
- Bacterial Endotoxin Testing
- Packaging and Seal Integrity Testing
- Adhesive and Wear Performance Testing
- Inserter Deployment and Reliability Testing
- Delivery Accuracy and Occlusion Verification
- Human Factors and Usability Validation

All testing met predefined acceptance criteria, demonstrating that the Pivot Insulin Delivery System is safe, performs as intended, and does not raise new questions of safety or effectiveness when compared to the predicate MODD1 Insulin Delivery System (K240158).

6.0 Substantial Equivalence Conclusion

After analyzing the indications for use, technological characteristics and performance data, Modular Medical concludes that Pivot Insulin Delivery System is substantially equivalent to the Modular Medical MODD1 Insulin Delivery System cleared under K240158.

The modifications related to the Pivot Insulin Delivery System do not raise different questions regarding safety and effectiveness of the device. Verification and validation testing confirmed that these modifications meet all design requirements and do not impact the device's safety, effectiveness, or performance. Therefore, the Pivot Insulin Delivery System is substantially equivalent to the predicate device.