September 4, 2024

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

Re: K240158
Trade/Device Name: Modular Medical MODD1 Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: January 19, 2024
Received: January 19, 2024

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.

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.

Submission Number *(if known)*

K240158

Device Name

Modular Medical MODD1 Insulin Delivery System

Indications for Use *(Describe)*

The Modular Medical MODD1 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

K240158

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	Modular Medical MODD1 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	t:slim® Insulin Delivery System (K160056)
Date Prepared	September 4, 2024

1.0 Indications for Use

The Modular Medical MODD1 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.

2.0 Device Description

The Modular Medical MODD1 Insulin Delivery System (i.e., MODD1 System) consists of the following:

- A reusable, software-controlled programmable Pump,
- A single-use, disposable 3.0mL (300 unit) Insulin Cartridge with an integrated battery to supply power to the Pump, infusion tubing, and Tubing Cap for attaching to the Infusion Set,
- A single-use, disposable Adhesive Pad for affixing the MODD1 System to the user's body and allowing for temporary removal of the MODD1 System,
- A single-use, disposable Infusion Set inserted into the patient's subcutaneous tissue, and
- The MMI App, a smartphone application used to program the basal delivery schedule on the Pump.

Accessories to the MODD1 System are FDA-cleared and include the following:

- A single-use disposable syringe (K110771) and needle (K021475) used to fill the Insulin Cartridge reservoir, and
- A reusable Inserter (K163400), optionally used to insert the Infusion Set into the patient's subcutaneous tissue.

The MODD1 System has been demonstrated to be compatible with Humalog U-100 insulin.

The MODD1 System can deliver insulin at basal rates between 0.5 – 4 units per hour (programmable in 0.1-unit increments) and user-selected bolus doses of between 2 and 20 units (in 2-unit increments). Basal insulin delivery may also be suspended for a set period of 30 minutes when required by the user.

The delivery of insulin is achieved by gear motor rotation of a single fixed-position camshaft (components of the Pump controlled by software) that interfaces with the Insulin Cartridge pistons to control the movement of insulin from the insulin reservoir, into an interim chamber, and into the infusion tubing towards the Infusion Set inserted into the patient's subcutaneous tissue. Software monitors dispense output via feedback provided by multiple sensors, providing an alarm when issues with delivery (e.g., malfunctions, low reservoir volume, occlusions) are detected.

The Pump serves as the primary user interface of the MODD1 System. A Control Button is used to prime the fluid path, program bolus deliveries, check system status, and to temporarily suspend insulin delivery. The multi-color LED and piezo buzzer of the Pump provide audio-visual feedback to the user during the set-up process, programming of a bolus delivery, and changing of delivery modes (e.g., bolus, basal, suspend). Audio-visual feedback is also used to inform the user of system alarms (automatically generated) and system status (when requested by the user).

The MMI App is downloaded directly onto an Apple® iPhone 12 Pro Max running iOS version 16. The MMI App allows for the configuration of a basal delivery schedule on the Pump, consisting of up to two basal rates in a 24-hour period. The MMI App and Pump communicate using Bluetooth® Low Energy (BLE) and Near Field Communication (NFC). After the basal delivery schedule has been programmed on the Pump, all insulin delivery functions are controlled using the Pump user interface. Optional features of the MMI App include a dashboard display of current and historical Pump information and delivery history.

3.0 Summary of Technological Characteristics Compared to Predicate Device

Similarities and differences between the predicate device (t:slim® Insulin Delivery System) and the subject device (Modular Medical MODD1 Insulin Delivery System) are illustrated in Table 2.

The subject device has the same intended use (subcutaneous delivery of insulin at set and variable rates), and similar indications for use as the predicate device, with the sole difference being the indicated age of users in the patient population. This difference does not introduce a new intended use.

Minor differences in the technological characteristics exist but do not raise new questions of safety and effectiveness. The information and testing evidence provided in this submission demonstrate that the subject device is as safe and effective as the predicate device.

Table 2: Substantial Equivalence Comparison

Element of Comparison	Predicate Device	Subject Device
Indications for Use	The t:slim® 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 6 years of age and	The Modular Medical MODD1 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

Element of Comparison	Predicate Device	Subject Device
	greater. The device is indicated for use with NovoLog or Humalog U-100 insulin.	individuals 18 years of age and greater.
Intended Use	Infusion System intended for the treatment of diabetes mellitus in persons requiring insulin.	Same
Prescription or Over the Counter	Prescription only	Same
Use Environment	At home	Same
Specific Drug/Biological Use	NovoLog or Humalog U-100 insulin	Humalog U-100 insulin
Pump Type	Motor-driven (linear piston)	Motor-driven (multiple piston)
Use Time	Up to 72 hours	Same
Components	Infusion pump, Sterile disposable insulin cartridge	Infusion pump, Sterile disposable insulin cartridge, Disposable adhesive pad, Sterile disposable infusion set, MMI App (smartphone application)
Accessories	UnoMedical Comfort™ disposable insulin infusion set (or equivalent), 3mL sterile syringe and 26-gauge needle (for filling cartridge), AC power supply and DC car adaptor power supply with USB	3 mL sterile syringe (K110771), 26-gauge sterile needle (K021475), Inserter (K163400)
Sterilization Method (for disposable insulin cartridge)	Gamma sterilization	Same
Dimensions	3.13” x 2.0” x 0.6” (L x W x H)	Pump only: 1.51” x 2.38” x 0.56” (L x W x H)
Weight	3.95 ounces (112 grams) (with full disposable attached)	1 ounce (28 grams) (with full disposable attached)
Reservoir Capacity	3.0 mL custom disposable insulin cartridge	Same
User Interface	Touch screen and key input (Pump)	Touch screen (MMI App) and button input (Pump)
Wearability	Belt / pocket mounted	Body worn
Communication	BLE	BLE and NFC

Element of Comparison	Predicate Device	Subject Device
Pump Information and History	Visible on the t:slim pump screen	Current pump information visible and audible on the pump; Pump history optionally visible on the MMI App
Alarm Type	Visual, audible, and vibratory	Visual and audible
Power Sources	Lithium Polymer battery (rechargeable)	Internal coin cell battery (non-rechargeable)
Pump Water Resistance	IPX7	IP24
Basal Suspend Mode	Yes	Same
Quick Bolus	User selectable dose through single button	Same
Flow Rates and Profiles	Basal: 0.1 - 15 units/hour (in 0.001-unit increments) Bolus: 0.05 - 25 units (in 0.01-unit increments)	Basal: 0.5-4 units/hour (in 0.1-unit increments) Bolus: 2 - 20 units (in 2-unit increments)
Delivery Accuracy	Basal Delivery Accuracy at intermediate rate: ±5% Bolus Delivery Accuracy: ±5%	Typical (mean) Basal Delivery Accuracy at All Flow Rates: ±5% Typical (mean) Bolus Delivery Accuracy at All Bolus Volumes: ±5%
Maximum Time to Occlusion Alarm	Bolus (3U or greater): 23 seconds Intermediate Basal (2U/hr): 1 hour 10 minutes Minimum Basal (0.1U/hr): 25 hours 30 minutes	Bolus (2U or greater): 2 minutes 19 seconds Intermediate Basal (2U/hr): 31 minutes 31 seconds Minimum Basal (0.5U/hr): 2 hours

4.0 Summary of Non-Clinical Performance Data

Appropriate testing was performed to confirm the subject device met specified requirements and performed as intended. The following performance and safety testing have confirmed the Modular Medical MODD1 Insulin Delivery System to be safe, effective, and substantially equivalent to the predicate device:

- **Risk Management**: Risk management was conducted in accordance with ISO 14971:2019. Verification of risk control measures demonstrates that all risk associated with the subject device has been mitigated to an acceptable level and that the subject device is safe for its intended use.
    - **Safety Assurance**: A safety assurance case has been provided as part of this submission per FDA guidance “Infusion Pumps Total Product Life Cycle”

and supports the determination that the subject device has adequately addressed hazards associated with its intended use within its environment of use.

- **Human Factors**: Human factors validation testing was conducted on the subject device to assess comprehension and usability of the device for critical device tasks per IEC 62366-1:2020, ANSI AAMI HE75:2009/(R)2018, and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". Results of validation testing performed demonstrate that the subject device has been found to be safe and effective for the intended users, uses, and use environments.
- **Insulin Compatibility:** Testing was conducted on the subject device to demonstrate compatibility with Humalog U-100 insulin.
- **Biocompatibility**: A biological evaluation was conducted on the subject device and included appropriate biocompatibility testing based on the nature and duration of patient-contacting materials to meet the requirements of ISO 10993-1:2018 and FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"".
- **Sterility**: Sterilization validation testing was performed on the subject device per applicable sterility standards.
- **Bench Testing**: Verification testing has demonstrated that the subject device meets design requirements. Infusion delivery accuracy at various flow rates and occlusion detection performance were verified.
- **Electrical Safety and Electromagnetic Compatibility**: Testing was conducted on the subject device to demonstrate safety and performance per IEC 60601-1:2020, IEC 60601-1-2:2020, and applicable collateral standards. Additionally, testing for electromagnetic compatibility in the aircraft environment was conducted per RTCA DO-160G.
- **Wireless Coexistence**: Testing was conducted per AAMI TIR69:2017/(R)2020 for the risk management of wireless coexistence and IEEE/ANSI C63.27:2021 for the evaluation of wireless coexistence.
- **Software**: Software verification and validation testing were conducted on the subject device per IEC 62304:2015 and FDA guidance "General Principles of Software Validation". Software documentation and testing evidence have been provided in accordance with FDA guidance "Content of Premarket Submissions for Device Software Functions".
- **Cybersecurity**: A cybersecurity risk analysis and testing were performed on the subject device per FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", and guidelines of "Postmarket Management of Cybersecurity in Medical Devices". Cybersecurity documentation and testing evidence are provided in this submission to support the determination of substantial equivalence for the subject device.

5.0 Substantial Equivalence Conclusion

After analyzing the intended use/indications for use, technological characteristics, and performance data, Modular Medical, Inc. concludes that the Modular Medical MODD1 Insulin Delivery System is substantially equivalent to the legally marketed Tandem Diabetes Care Inc. t:slim® Insulin Delivery System (K160056). While the subject device's technological characteristics differ slightly from the predicate, the differences do not raise different questions of safety and effectiveness as substantiated by testing and information supplied in this submission. Therefore, the Modular Medical MODD1 Insulin Delivery System is substantially equivalent to the predicate device.