510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K240158

B Applicant

Modular Medical, Inc.

C Proprietary and Established Names

Modular Medical MODD1 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:

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications For Use below

B Indication(s) 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.

C Special Conditions for Use Statement(s):

This device is for prescription use only.

The MODD1 System is contraindicated for:

1. Diagnosing Diabetes Mellitus.

2. Use by patients who do NOT have adequate hearing and/or vision to allow recognition of all functions of the MODD1 System including Status and Alarms.
3. Use by patients who cannot manage their Diabetes therapy.
4. Use by patients unwilling to take a minimum of four (4) blood glucose readings per day.
5. Use by patients who are unable to use the MODD1 System in accordance with this User Guide.
6. Use by patients who are not capable of following the User Guide
7. Use by patient populations requiring basal rates greater than 4 U/hr or less than 0.5U/hr

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 device is an insulin pump that is worn adhered to the user's body through an adhesive patch with a short infusion set. The subject device consists of a pump mechanism (reusable, up to 90 days), an insulin cartridge assembly (sterile single use, up to 72 hours), an adhesive pad (single use, up to 72 hours), an infusion set (sterile single use, up to 72 hours), and a smartphone application (reusable, indefinite length of time) contained on an iPhone operating iOS 16 or later. The infusion set is distributed by Modular Medical. There are previously cleared 3rd party components that are able to be used with the subject device including a syringe (BD; K110771), a needle (BD; K021475), and the Ypsomed Orbit Inserter (Ypsomed; K163400).

The pumping mechanism consists of a linear peristaltic pump that pushes a fixed amount of insulin (5 microliters or 0.5 Units) per cycle of the pump operating. The pump must be programmed through the MMI App installed on an Apple (iOS) smartphone by the pump user. Once a pump is programmed it can operate independently from the app and does not require a phone to be connected or paired with the pump unless new insulin delivery rates are being programmed.

The insulin cartridge exterior is a rigid cyclic olefin copolymer and supports the pistons that are manipulated by the pump and supports the coin cell battery. The interior of the insulin cartridge that has contact with insulin is flexible and has membranes that allows for air to enter the cartridge and push against the flexible membrane and for insulin to exit the cartridge via the infusion set.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

The t:slim® Insulin Delivery System

B Predicate 510(k) Number(s):

K160056

C Comparison with Predicate(s):

Device & Predicate Device(s):	K240158	K160056
Device Trade Name	Modular Medical MODD1 Insulin Delivery System	The t:slim® Insulin Delivery System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.	Same
Operating Environment	Home Use	Same
Insulin Delivery Modes	Basal and Bolus	Same
Reservoir Volume	3 mL	Same
General Device Characteristic Differences		
Intended User Age Range	18 years and greater	6 years and greater
Bolus Dose Range	2-20 units	0.05-25 units
Basal Delivery Flow Rates	0.5 – 4 units/hour	0.1-15 units/hour
Insulin Bolus Calculator	No	Yes
Connectivity	BLE and NFC	BLE

V Standards/Guidance Documents Referenced:

Standards

- AAMI TIR101:2021 Fluid delivery performance testing for infusion pumps

- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION, 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
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
- AAMI HE75:2009/(R)2018, Human factors engineering - Design of medical devices
- RTCA DO-160 Environmental Conditions and Test Procedures for Airborne Equipment

FDA Guidance Documents:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023)
- Applying Human Factors and Usability Engineering to Medical Devices (February 2016)
- Electromagnetic Compatibility (EMC) of Medical Devices (June 2022)
- Content of Premarket Submissions for Device Software Functions (June 2023)
- 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

The basal delivery accuracy of the pump was tested with water to simulate insulin for minimum, intermediate and maximum basal rate delivery performance for both new and aged pumps without any warm-up period. Both new pumps (n=15) and aged pumps (n=15) were tested for accuracy. Table 1 reports the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum basal rate settings for all pumps tested.

Table 1.: Amount of fluid delivered after 1, 6, and 12 hours at minimum, intermediate, and maximum basal rate settings

Median Insulin Units Delivered, New Pumps n = 15			
Basal Rate	**1 hour**	**6 hours**	**12 hours**
0.5 U/hour [min, max]	0.62 U [0.57, 0.65]	3.16 U [3.03. 3.26]	6.17 U [5.93, 6.39]
2.0 U/hour [min, max]	2.10 U [2.02, 2.25]	12.05 U [11.53, 12.78]	24.05 U [22.88, 25.56]
4.0 U/hour [min, max]	4.20 U [4.05, 4.45]	24.51 U [23.47, 25.82]	48.81 U [46.53, 51.58]
Median Insulin Units Delivered, Aged Pumps n = 15			
0.5 U/hour [min, max]	0.63 U [0.59, 0.65]	3.19 U [3.03, 3.33]	6.22 U [5.92, 6.58]
2.0 U/hour [min, max]	2.17 U [2.03, 2.25]	12.16 U [11.32, 12.82]	24.14 U [22.48, 25.47]
4.0 U/hour [min, max]	4.22 U [4.00, 4.51]	24.33 U [22.94, 25.85]	48.40 U [45.57, 51.37]

2. Bolus Accuracy

The bolus delivery accuracy of the pump was tested with water to simulate insulin for the minimum, intermediate, and maximum bolus amounts. Both new pumps (n=15) and aged pumps (n=15) were tested for accuracy. The pumps each were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.05 U, 6.0 U, and 30 U).

Table 2 below shows the number (and %) of boluses within the specified range of the minimum bolus, one intermediate bolus and the maximum bolus volume.

Table 2.: Amount of fluid delivered after bolus requests of 2, 10, and 20 units for new and aged pumps

	2U Insulin Bolus Request, n=450 boluses, n=15 new pumps									
	<25%	**25-75%**	**75-90%**	**90-95%**	**95-105%**	**105-110%**	**110-125%**	**125-175%**	**175-250%**	**>250%**
# in range	0/450	0/450	13/450	63/450	350/450	24/450	0/450	0/450	0/450	0/450
% in range	0%	0%	2.9%	14.0%	77.8%	5.3%	0%	0%	0%	0%
	10U Insulin Bolus Request, n=423 boluses n= 15 new pumps									
# in range	0/423	0/423	1/423	41/423	332/423	47/423	2/423	0/423	0/423	0/423
% in range	0%	0%	0.2%	9.7%	78.5%	11.1%	0.5%	0%	0%	0%

	20U Insulin Bolus Request, n=209 boluses n= 15 new pumps									
# in range	0/209	0/209	1/209	16/209	178/209	14/209	0/209	0/209	0/209	0/209
% in range	0%	0%	0.5%	7.7%	85.2%	6.7%	0%	0%	0%	0%
	2U Insulin Bolus Request, n=450 boluses, n=15 aged pumps									
# in range	0/450	1/450	15/450	49/450	371/450	14/450	0/450	0/450	0/450	0/450
% in range	0%	0.2%	3.3%	10.9%	82.4%	3.1%	0%	0%	0%	0%
	10U Insulin Bolus Request, n=423 boluses n= 15 aged pumps									
# in range	0/419	0/419	1/419	58/419	318/419	42/419	0/419	0/419	0/419	0/419
% in range	0%	0%	0.2%	13.8%	75.9%	10.0%	0%	0%	0%	0%
	20U Insulin Bolus Request, n=209 boluses n= 15 aged pumps									
# in range	0/210	0/210	1/210	17/210	180/210	12/210	0/210	0/210	0/210	0/210
% in range	0%	0%	0.5%	8.1%	85.7%	5.7%	0%	0%	0%	0%

3. Occlusion Detection

The time to detection of complete occlusions was measured. Pumps were physically occluded by closing the patient end of the fluid path. After pumps alarmed, the occlusions were cleared, and the total amount of fluid delivered was measured. Unintended bolus after release of an occlusion is less than 3 U of insulin. Table 3 shows typical time to occlusion detection for new pumps under three different situations.

Table 3. Timing of occlusion detection alarms

Operating Rate	Typical	Maximum
Bolus (2U or greater)	1 Minute 51 Seconds	2 Minutes 19 Seconds
Basal (2U/hr)	30 Minutes 29 Seconds	31 Minutes 31 Seconds
Basal (0.5U/hr)	2 Hours 0 Minutes	2 Hours 0 Minutes

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 Diabetes Mellitus aged 18 years or older and treated as an adult. There was a mix of insulin pump experience and naïve. Users had 5-42 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 on 1 training by a trainer from Modular Medical that lasted up to 90 minutes and consisted of using the subject device with the trainer, using the quick start guide and the instructions for use, and reviewing the training slides. Training consisted of walking users through how to use the system and instructional materials followed by users demonstrating to the trainer how they would use the system and being able to complete all of the tasks associated with training. 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.

   During simulate use testing, users were provided with a smartphone that was capable of dialing a customer support number that was listed in the instructions for use and an employee of Modular Medical was available to answer the call if needed. Users were validated on their ability to use the subject device when provided clinical context without prompting from the moderator to complete specific tasks and included their ability to notice and resolve alarms.

   Critical tasks were identified based on the clinical harm severities that could occur due to use error such as hypoglycemia, hyperglycemia, 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 was sterilized with radiation and validated 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).

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.

6. Additional Bench Testing

   In addition to the performance testing described above, mechanical testing and simulated use testing, the subject device was subjected to additional testing to verify its reliability to demonstrate that it could function for 90 days. This testing included cyclic reliability testing to simulate actual use of the pump including accelerated aging of insulin cartridges, simulation of packaging and shipping, vibration and shock testing, exposure to personal care products, cleaning, button presses, insulin cartridge changes, drops, and ingress testing. 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.

Testing to Support System Reliability
Pump lifetime testing
Transient Temperature
Transient Pressure
Ingress Protection
Cleaning
Against mechanical stressors (e.g., vibrations, shock)
Against personal care products such as sunscreen and lotions
Delivery Accuracy and Occlusion Detection Testing

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 equivalent 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.