510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K260062

B Applicant

DreaMed Diabetes Ltd.

C Proprietary and Established Names

MODI System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QRX	Class II	21 CFR 862.1358 – Insulin Therapy Adjustment Device	CH – Clinical Chemistry

E Purpose for Submission:

- New Device
- Establish a Predetermined Change Control Plan (PCCP) to integrate with a 3rd Party Host Diabetes Management System (DMS) and to integrate new data source partners

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MODI insulin dose calculator is software intended for the management of type 2 diabetes in persons aged 18 years and older requiring long-acting insulin with or without rapid-acting insulin injections. MODI insulin dose calculator calculates a dose of basal (long-acting) insulin with or without a dose of bolus (rapid-acting for meal and correction) insulin based on glucose measurements from an iCGM (Integrated Continuous Glucose Monitor) and insulin delivery data (i.e. time of dose with or without amount of dose). MODI insulin dose calculator intended for single patient, home use and requires a prescription by a healthcare provider.

Special conditions for Use Statement:

- MODI is Rx - For Prescription Use Only
- MODI algorithm is not intended for use with patients treated with insulin pump, Automated Insulin Dosing (AID), intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy.
- MODI insulin dose calculator is not recommended for use during pregnancy. MODI has not been tested with individuals who are pregnant.

C Special Conditions for Use Statement(s):

MODI is Rx – For Prescription Use Only

MODI algorithm is not intended for use with patients treated with an insulin pump, automated insulin dosing (AID), intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy.

MODI insulin dose calculator is not recommended for use during pregnancy. MODI has not been tested with individuals who are pregnant.

The MODI algorithm is not intended for use in individuals initiating basal insulin therapy for the first time. DreaMed Diary and MODI algorithm are not intended for use by patients who use insulin(s) other than the types indicated in the User Manual. Using MODI with other types of insulin may lead to potential harm.

III Device Description

MODI system is an insulin does calculator intended for use by people aged 18 years and older with type 2 diabetes who require long-acting insulin, with or without rapid-acting insulin injections. MODI is a CGM-informed insulin dose calculator that uses continuous glucose monitoring (CGM) data, insulin administration logs, and patient-specific treatment parameters to optimize and recommend basal and/or bolus insulin doses.

The MODI system comprises software components include:

- MODI, including the MODI Algorithm and the MODI Engine
- DreaMed Diary App (modified from K232722) as the Host App
- Endo.digital platform (modified from K232722) as the Host Diabetes Management Software (DMS)

The MODI Algorithm analyzes glucose levels, insulin delivery history, treatment plan, and body weight to generate insulin dose recommendations that are typically issued every 7 days and are delivered to the patient via the Host App (through the MODI Engine). The MODI Engine facilitates communication between the Host App, Host DMS, and the MODI Algorithm, supporting system initialization, titration assessment, and transmission of dose recommendations.

The Host App is a dedicated version of the DreaMed Diary app (K232722) enabling patient interaction with the MODI Algorithm (e.g., patient self-onboarding, insulin event logging, and visualization of dose recommendations) via the MODI Engine. The Host DMS is a diabetes management middleware integrating with CGM data, the Host App, and the MODI Engine.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Dexcom Smart Basal

B Predicate 510(k) Number(s):

K252818

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260062	K252818
Device Trade Name	MODI System	Dexcom Smart Basal
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to calculate insulin doses based on CGM values and/or other relevant information	Same
Diabetes Type	Type 2 diabetes	Same
Principle of Operation	Algorithmic software device	Same
Age range of intended users	18 years and older	Same
Display to users	Calculated doses via mobile application	Same
General Device Characteristic Differences		
Insulin use	Basal (long-acting) with or without bolus (rapid-acting)	Basal (long-acting) only
Insulin type	Long-acting: Basaglar, Degludec U-100, Degludec U-200, Glargine, Lantus,	U-100 glargine only

	Levemir, Rezvoglar, Semglee, Soliqua, Toujeo U-300, Toujeo Max U-300, Tresiba U-100, Tresiba U-200, Xultophy, Tregludec U-100, Tregludec U-200 Rapid-acting: Admelog, Apidra, Aspart, Fiasp, Humalog U-100, Humalog U-200, Lispro U-100, Lyumjev U-100, Lyumjev U-200, Novolog, ReliOn Novolog, Novorapid	
Data inputs	CGM values and historic data, initial configuration from user, daily insulin log	CGM values and historic data, initial configuration from HCP, daily basal insulin log
Device outputs	Weekly recommendations of optimized insulin dose plan (basal plan, meal bolus plan for fixed meal and meal estimation types, personal diabetes management tips)	Suggested daily basal dose output
Titration frequency	Every 7 days; daily decrease is allowed as needed	Daily
Titration episode length	Continuous unless terminated by user, or in case the patient has not reported insulin doses in 90 days	Up to 90 days, unless terminated by the HCP or patient

Pre-determined Change Control Plan (PCCP): In addition to the similarities and differences between the candidate and the predicate device listed in the table above, the candidate device has an authorized PCCP for integrating with a 3rd Party Host Diabetes Management System (DMS) and for integrating with new data source partners, such as a CGM or insulin pen. The PCCP includes a description of the modifications, a modification protocol, and an impact assessment. The PCCP specifies the testing methods, validation activities, and performance requirements to implement the specified modifications such that DreaMed MODI remains as safe and as effective as the predicate device and continues to comply with 21 CFR 862.1358. The sponsor's PCCP comprises the following:

- Integration with a new 3rd Party Host DMS allows an Integration Partner to implement MODI within their mobile app, and in turn, the Integration Partner will utilize and visualize MODI's output within their app. The PCCP describes DreaMed's responsibilities for supporting this change including providing adequate labeling and specifying integration requirements and conducting a cybersecurity risk assessment. Software changes to facilitate the integration that would require a new 510(k) are not covered in this PCCP. Cybersecurity risks and risks associated with human factors (changes to user tasks, user interface flow, connected-device setup, data source authorization, device status, warnings, training, or labeling) will be evaluated by the same methods used in this 510(k). Mitigation of new risks are outside the scope of this PCCP.

- Integration with a new data source partner allows additional data sources (e.g., CGMs sensor or connected insulin pens) to connect with MODI. The new data source partners expand compatibility of MODI and do not change the clinical input types or modify the MODI algorithm. Verification and validation activities will be conducted according to the PCCP. New data source devices must be FDA-authorized and DreaMed will conduct a risk assessment for hazards introduced or changed by the new data source and a use-related risk analysis for any changes to user tasks and the user interface. Integration validation testing will be conducted per device type (e.g., CGMs versus insulin pens), and MODI labeling will be updated to list authorized devices. If integration verification and validation meet the PCCP's acceptance criteria, a new data source may be integrated with MODI.

V Standards/Guidance Documents Referenced:

Special controls established under 21 CFR 862.1358

ISO 14155 Third Edition 2020-07 Clinical investigation of medical devices for human subjects – Good clinical practice

ANSI/AAMI/ISO 14971:2019 Medical devices – Applications of risk management to medical Devices

ANSI/AAMI/IEC 62304:2006/A1:2016 Medical device software – Software life cycle processes [Including Amendment 1 (2016)]

ANSI/AAMI/IEC 62366-1:2015 + AMDI:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1

VI Performance Characteristics:

Clinical Testing

A prospective, single-center, single-arm study was conducted to evaluate the safety of the MODI system in subjects with type 2 diabetes. The study enrolled 29 participants aged 18 years and older under multiple daily injections (MDI) or basal insulin therapy. The average age was 67 years, 48% of subjects were female, the average BMI was 29.8 kg/m^2, and the average baseline HbA1c was 7.6%. Patients' long-acting regimen included Glargine U-100 (7 patients), Detamir

U-100 (3 patients), Glargine U-300 (1 patient), Degludec U-200 (7 patients) and Insulin degludec and Liraglutide U-100 (5 patients). For patients under multiple daily injections, short acting insulin regimen included Aspart U-100 (13 patients) and Glulisine U-100 (1 patient).

The study consisted of a 2–4 weeks run-in period (baseline) followed by a 10-weeks intervention period, during which insulin dosing recommendations were generated by the MODI System. At study initiation, study staff entered the initial treatment plan settings. Subjects were permitted to the use the device as they wish at home for the study duration and there were study visits at 4 and 10 weeks to review data for adverse events at HbA1c collection (only at 10 weeks). Study staff contacted subjects during the study outside of protocol-specified visits to confirm that no adverse events had occurred. During these calls, study staff did not provide individualized guidance regarding interpretation of MODI outputs, insulin dose decisions, or diabetes management beyond protocol-defined activities and routine safety follow-up.

The primary objective was to evaluate the safety of the MODI system. Safety was assessed by evaluating percentage of CGM values below 54 mg/dL and serious adverse events, including severe hypoglycemia and diabetic ketoacidosis. Secondary objectives included time above 250 mg/dL, hypoglycemia events (< 54 mg/dL for ≥ 15 minutes) and prolonged hyperglycemia events (> 250 mg/dL for 120 minutes). Exploratory endpoints included efficacy-related endpoints (CGM metrics and HbA1c), as shown in the table below. There were no reports of serious adverse events of any kind, including device-related events, severe hypoglycemia and diabetic ketoacidosis, during the intervention period of the study.

Percent	Baseline Mean ± SD	End-of-Study Mean ± SD	Difference Mean ± SD	P-value[a]
All Subjects with T2D (N = 29)				
Time in range 70-180 mg/dL	74 ± 15	76 ± 13	2.2 ± 12	0.32
Time below 54 mg/dL	0.47 ± 1.8	0.23 ± 0.51	-0.24 ± 1.6	0.44
Time below 70 mg/dL	2.4 ± 4.9	1.3 ± 1.5	-1.1 ± 4.0	0.16
Time above 180 mg/dL	24 ± 16	23 ± 13	-1.1 ± 11	0.59
Time above 250 mg/dL	3.9 ± 4.4	3.0 ± 3.6	-0.91 ± 3.9	0.22
HbA1c	7.6 ± 0.96	7.2 ± 0.8	-0.43 ± 0.71	0.003
All Subjects with T2D on MDI Therapy (N = 14)				
Time in range 70-180 mg/dL	68.1 ± 16.9	73.8 ± 13.6	5.64 ± 12.8	0.12
Time below 54 mg/dL	0.09 ± 0.14	0.12 ± 0.26	0.02 ± 0.3	0.77
Time below 70 mg/dL	1.29 ± 1.49	1.09 ± 0.92	-0.2 ± 0.94	0.45
Time above 180 mg/dL	30.6 ± 17.0	25.1 ± 13.8	-5.45 ± 13.2	0.15
Time above 250 mg/dL	5.4 ± 5.3	3.1 ± 3.1	-2.29 ± 4.22	0.063

HbA1c	7.89 ± 1.06	7.42 ± 0.87	-0.47 ± 0.76	0.038
All Subjects with T2D on Basal-Only Therapy (N = 15)				
Time in range 70-180 mg/dL	78.7 ± 12.0	77.7 ± 13.3	-0.95 ± 10.0	0.72
Time below 54 mg/dL	0.83 ± 2.44	0.3 ± 0.52	-0.53 ± 2.17	0.36
Time below 70 mg/dL	3.77 ± 6.94	1.52 ± 1.93	-2.25 ± 5.56	0.14
Time above 180 mg/dL	18.0 ± 12.2	20.9 ± 13.5	3.0 ± 7.7	0.15
Time above 250 mg/dL	2.41 ± 2.7	2.91 ± 4.22	0.5 ± 3.19	0.56
HbA1c	7.41 ± 0.83	7.02 ± 0.7	-0.4 ± 0.7	0.04

[a]Paired t-test

Recommendations are typically issued by MODI every seven days and delivered to the patient. If MODI detects an increased risk of hypoglycemia, daily adjustments may be provided. During the study, MODI detected 260 cases of a potentially increased risk of hypoglycemia. In 36 cases, a recommendation from the app was issued. To evaluate the effect of these recommendations, patient CGM data from before the recommendation was compared to their CGM data after the recommendation. The same comparison was made for instances where no recommendation was sent to the patients. These results are reported in the table below.

	Mean Time below 54 mg/dL (%) Mean ± SD		**Mean Time below 70 mg/dL (%) Mean ± SD**	
	3 days before	**3 days after**	**3 days before**	**3 days after**
Recommendation issued (36 cases in 11 patients)	6.1 ± 13.3	3.3 ± 9.6	14.3 ± 19.3	8.9 ± 15.3
No recommendation issued (224 cases in 18 patients)	0.3 ± 0.9	0.2 ± 1.0	4.7 ± 5.6	3.8 ± 6.1

Software

DreaMed provided software documentation consistent with FDA Guidance for the Content of Premarket Submissions for Device Software Functions and consistent with software with a major level of concern. Software documentation was acceptable.

Cybersecurity

DreaMed provided cybersecurity documentation consistent with FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Cybersecurity documentation was acceptable.

Human Factors

Human factors validation studies were conducted to assess if representative users of MODI can safely use the system and perform all critical tasks under representative conditions. Studies were conducted with 20 adult participants with Type 1 or insulin-requiring Type 2 diabetes, including adult-caregiver dyads and subjects who take basal insulin only. All study participants received training that was consistent with the training that patients will receive with the commercial product and interacted with the device in a simulated use environment. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the device could be used safely by intended users.

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.