September 8, 2026

DreaMed Diabetes, Ltd.
Adi Berkovitch
VP RA & Qa
14 Kaplan St.
Petah Tikva, 4920235
Israel

Re: K260062
Trade/Device Name: MODI System
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin therapy adjustment device
Regulatory Class: Class II
Product Code: QRX
Dated: January 8, 2026
Received: January 8, 2026

Dear Adi Berkovitch:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)*
K260062

Device Name
MODI System

Indications for Use *(Describe)*
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.

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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510(k) SUMMARY
MODI System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

DreaMed Diabetes Ltd.
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Phone – (239) 6622212
Email – info@dreamed.ai
Website – www.dreamed.ai

Contact Person: Adi Berkovitch
Email: adi.berkovitch@dreamed.ai
Date Prepared: August 30, 2026

Name of Device and Name/Address of Sponsor

MODI System (version 03.00.07)
DreaMed Diabetes Ltd.
14 Kaplan st.
Petah Tikva
4920235
Israel

Common or Usual Name

CGM-Informed Insulin Dose Calculator

Predictive pulmonary-function value calculator

Classification

Class II, 21 CFR 862.1358, Product Code: QRX,

Class II, 21 CFR 868.1890, Product Code: NDC.

Predicate Devices

DexCom Smart Basal K252818

Reference Device: DreaMed endo.digital platform (K232722)

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Intended Use / Indications 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.

Device Description

The MODI System is an insulin dose calculator intended for individuals with type 2 diabetes. It is designed to optimize and recommend basal and/or bolus insulin doses using continuous glucose monitoring (CGM) data, insulin administration logs, and patient-specific treatment parameters. Access to MODI requires a prescription from a healthcare provider (HCP).

Patients interact with MODI through a dedicated mobile application called the Host App. During self-onboarding, patients enter body weight, initial basal dose and bolus plan (if applicable), while other settings default. These parameters are securely transmitted to MODI. After self-onboarding, patients use the Host App to record insulin administration events and view dose recommendations generated by the MODI.

The MODI System consists of three main components: MODI (including MODI Algorithm and MODI Engine), the Host App, and the Host Diabetes Management System (DMS).

MODI (version 03.00.07) is a proprietary class II medical device designed to analyze glucose levels, insulin delivery history, treatment plan, and body weight to generate dose recommendations that help patients manage their insulin therapy using the MODI Algorithm. Recommendations are typically issued every seven days and delivered to the patient via the Host App (through the MODI Engine), and if MODI detects an increased risk of hypoglycemia, daily adjustments may be provided. Recommendations continue until the patient disables the feature, fails to report insulin doses for 90 days, or does not validate weight for 180 days. MODI Engine facilitates communication between the Host App, Host DMS, and the Algorithm, supporting system initialization, titration assessment, and recommendation delivery.

In this version of MODI system, the Host App is a modified version of the DreaMed Diary app (K232722) that enables patient interaction with MODI, onboarding, insulin event logging, and visualization of recommendations. The Host App also includes a Rapid-Acting Insulin Dose Calculator feature, similar to the cleared endo.digital Bolus Calculator (K232722).

The Host DMS is a diabetes management middleware integrating with CGM data (in similar way as in endo.digital platform (K232722), Host App and MODI Engine and can govern the patient enrollment.

Substantial Equivalence

Feature/Function	**DreaMed Diabetes Ltd** **MODI System** **(Subject Device)**	**DexCom, Inc** **DexCom Smart Basal** **(Predicate Device)**
Indication 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.	The Dexcom Smart Basal insulin dose calculator is software intended for the management of type 2 diabetes in persons aged 18 years and older requiring long-acting insulin. This is not for use for patients on fast-acting insulin. The Dexcom Smart Basal insulin dose calculator calculates a dose of basal (long-acting) insulin using logged doses and glucose measurements from an integrated continuous glucose monitor (iCGM). The Dexcom Smart Basal insulin dose calculator requires a prescription and initial configuration by a healthcare provider.
Rx or OTC	Rx	Rx
Age Range of Intended Users	18 yrs and up	18 yrs and up
Principle of Operation	Algorithmic software device	Algorithmic software device
Device Inputs	Requires data from an integrated continuous glucose monitor (iCGM) device, input parameters set by the patient, and logged insulin doses by the patient	Requires data from an integrated continuous glucose monitor (iCGM) device, input parameters set by a healthcare provider, and logged insulin doses by the patient
Device Outputs	Weekly recommendations of suggested optimized insulin dosing plan: • Basal plan • Meal bolus plan for fixed meal and meal estimation types. • Personal diabetes management tips	Calculates a suggested daily basal dose output Provides a titration episode state that informs the patients of program completion
Verification & Validation	• Software Verification and Validation • Clinical Validation • Human Factors Validation • Benchtop Scenario Testing • Cybersecurity	• Software Verification and Validation • Clinical Validation • Human Factors Validation • Benchtop Scenario Testing • Cybersecurity
Predetermined Change Control Plan (PCCP)	Future changes to MODI System will be implemented in accordance with the below-mentioned PCCP.	N/A

Clinical and non-clinical Performance Testing

The MODI System was verified and validated according to DreaMed's internal design control processes and in accordance with special controls for continuous glucose monitor informed insulin dose calculators. These testing demonstrated that the MODI System performed accordingly to its specifications and that the technological and performance criteria are comparable to the predicate device. The clinical and non-clinical testing for the MODI System is similar to that of the predicate device (K252818). Like the predicate, the subject verification and validation activities included the following:

Clinical validation

A prospective, single-center, single-arm study was conducted to evaluate the safety of the MODI system in participants with type 2 diabetes. The study enrolled 29 participants under multiple daily injections or basal insulin therapy. Average age was 67 years, fourteen participants (48%) were female, average BMI was 29.8 kg/m2, and average 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 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.

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 (TB54), 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 analysis included efficacy-related endpoints (CGM-based metrics and HbA1c) with subgroup analysis for participants with baseline time-in-range (TIR) below 70%1, and other metrics related to insulin regimen changes, satisfaction and adherence.

Across all primary and secondary safety endpoints, all predefined non-inferiority safety thresholds were met, and no clinically meaningful increases in hypoglycemia or hyperglycemia were observed. No episodes of severe hypoglycemia or diabetic ketoacidosis occurred during the study, and no serious adverse events related to device use were reported. All safety success criteria were achieved, supporting the conclusion that the MODI system is safe for use under the conditions evaluated in this study.

All Subjects (N=29)	**Summary of 14-day CGM Metrics and HbA1c**			
	Baseline Mean ± SD	**End of Study Mean ± SD**	**Diff Mean ± SD**	**P-value***
Time below 54 mg/dL [%]	0.5 ± 1.8	0.2 ± 0.5	-0.2 ± 1.6	0.44
Time below 70 mg/dL [%]	2.4 ± 4.9	1.3 ± 1.5	-1.1 ± 4.0	0.16
Time in range of 70-180 mg/dL [%]	74 ± 15	76 ± 13	2 ± 12	0.32
Time above 180 mg/dL [%]	24 ± 16	23 ± 13	-1 ± 11	0.59
Time above 250 mg/dL [%]	3.9 ± 4.4	3.0 ± 3.6	-0.9 ± 3.9	0.21
HbA1C [%]	7.6 ± 1.0	7.2 ± 0.8	-0.4 ± 0.7	0.003

* 2-sided paired t-test

For participants with TIR at baseline below 70%, there was a statistically significant and clinically meaningful increase in TIR[1], as well as a statistically significant decrease in Time Above 180 mg/dl without an increase in time below range. Furthermore, a clinical meaningful numeric reduction in HbA1c was observed, after using the MODI system. Increased TIR can reduce the risk of hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar), which can help prevent both short-term and long-term complications[2,3].

Subgroup analysis - participants with TIR <70% at baseline (N=11)	**Summary of 14-day CGM Metrics and HbA1c**			
	Baseline Mean ± SD	**End of Study Mean ± SD**	**Diff Mean ± SD**	**P-value***
Time below 54 mg/dL [%]	0.9 ± 2.9	0.2 ± 0.4	-0.8 ± 2.5	0.32
Time below 70 mg/dL [%]	2.8 ± 6.3	1.4 ± 1.4	-1.4 ± 5.3	0.40
Time in range of 70-180 mg/dL [%]	58 ± 10	69 ± 11	11 ± 12	0.02
Time above 180 mg/dL [%]	39 ± 13	29 ± 12	-10 ± 11	0.02
Time above 250 mg/dL [%]	7.2 ± 5.1	4.0 ± 3.2	-3.2 ± 4.6	0.04
HbA1c [%]	8.1 ± 0.8	7.7 ± 0.7	-0.4 ± 0.6	0.06

* 2-sided paired t-test

Reference:

1. Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R., Biester, T., Bosi, E., Buckingham, B. A., Cefalu, W. T., Close, K. L., Cobelli, C., Dassau, E., DeVries, J. H., Donaghue, K. C., Dovc, K., Doyle, F. J., Garg, S., Grunberger, G., Heller, S., ... & Phillip, M. (2019). Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care, 42(8), 1593–1603.https://doi.org/10.2337/dci19-0028
2. American Diabetes Association Professional Practice Committee. (2026). Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2026. *Diabetes Care, 49*(Supplement_1), S132-S149. https://doi.org/10.2337/dc25-S006
3. Qu F, Yang Q, Zeng Q, Li Z, Li J. *Time in Range and Adverse Outcomes in Type 2 Diabetes: A Quantitative Synthesis.* Journal of Clinical Medicine. 2026;15(14):5713. DOI: 10.3390/jcm15145713

Human Factor

Human factors and usability testing of the MODI System was conducted to evaluate the intended user population on their ability to operate the MODI System safely, and on their ability to demonstrate comprehension by responding to specific knowledge-based questions. Human factors testing was conducted in accordance with:

- FDA draft guidance - Content of Human Factors Information in Medical Device Marketing Submissions (December 2022)
- Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016
- IEC 62366-1:2015/AMD 1:2020: Medical devices – Part 1: Application of Usability Engineering to Medical Devices

The critical and essential tasks were identified through a use-related risk analysis (URRA), which identified critical tasks solely based on the Severity of harm and included tasks resulting from known-use problems and hazards analysis. These tasks were evaluated to demonstrate safe and effective use of the MODI System. An analysis of hazards and risks was conducted on the MODI System to determine safety risks associated with use of the system. Results of the human factors study support that the intended users can use the MODI System safely and effectively.

Non-Clinical Validation

Software	Software verification and validation testing was conducted to confirm that the MODI System performed in accordance with established specifications, IEC 62304 and FDA Guidance document "Guidance for the Content of Premarket Submissions for Device Software Functions," June 14, 2023. Evaluation activities included code review, unit, system integration, and system level testing which verified functionality of the device against established software requirements. Results of the software executed protocols for the MODI System are acceptable for their intended use.
Benchtop Scenario Testing	Non-clinical validation testing was performed on the MODI Algorithm to evaluate its performance reliability, and safety across a wide range of clinically relevant scenarios as well as foreseeable off-nominal conditions. The evaluation encompassed variations in glycemic trends, insulin dosing patterns, physiological responses, and data integrity, as well as potential misuse. Results confirmed that the algorithm consistently generates clinically appropriate insulin dose recommendations, maintained adherence to predefined safety and dosing constraints, and demonstrated robust error handling and alerting mechanism under all tested conditions. These findings support clinical validity and safety of the MODI Algorithm for its intended use.
Cybersecurity	DreaMed has provided cybersecurity risk management documentation for the MODI System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the MODI System in accordance with the FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (June 26, 2025). The cybersecurity risks identified for the MODI System were systematically evaluated and addressed through architectural, technical, and procedural risk control measures implemented throughout the product lifecycle. Following implementation of these controls, the residual cybersecurity risks were

	assessed and determined to be acceptable. The cybersecurity risk-benefit analysis demonstrates that the benefits of the MODI System outweigh the residual cybersecurity risks when the system is used as intended and operated within its defined security controls. Based on this assessment, the MODI System provides a reasonable assurance of safety and effectiveness from a cybersecurity perspective.
Special Controls	The subject device was evaluated to ensure the Special Controls in 21 CFR 862.1358 are adequately addressed.

Predetermined Change Control Plans (PCCP) for MODI System

The PCCP covers future software and integration changes to the MODI System that would otherwise require a new 510(k), provided the device remains safe, effective, and substantially equivalent.

Planned modifications include:

- Interoperability: integration with new Host DMS, Host Apps, and new data sources such as CGM and connected insulin devices.

Testing Methods

All modifications will be verified and validated under company's Quality Management System and regulatory requirements. Verification and validation testing methods include:

- Software verification and validation activities including functional and safety checks
- Human factors validation for user interface changes (as needed)
- Cumulative impact assessments for multiple modifications
- Regression and integration testing
- Cybersecurity assessments

Means of Informing Users

Users will be informed of device modifications through:

- Updated user interface.
- Updated labeling (User Manual and information for Health Care Professionals), including lists of authorized and contraindicated devices
- Partners that will integrate MODI capabilities as per the Integration Manual

Conclusions

The subject MODI System has the same intended use and similar indications for use and technological characteristics as those of the predicate device as discussed above. DreaMed provided performance testing within this premarket notification to demonstrate that the subject device performs as intended and in conformance to 21 CFR 862.1358 special controls for Insulin Therapy Adjustment Devices. The differences between the subject and predicate device do not raise any new or different questions of safety or effectiveness, therefore, the subject MODI System is substantially equivalent to the predicate device.