July 18, 2019

DreaMed Diabetes Ltd.
Eran Atlas
Co-Founder & CEO
5 Mota Gur Street
Petah Tikva, 4952701
Israel

Re: K191370
Trade/Device Name: DreaMed Advisor Pro
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin therapy adjustment device
Regulatory Class: Class II
Product Code: QCC
Dated: May 20, 2019
Received: May 22, 2019

Dear Eran Atlas:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191370

Device Name
DreaMed Advisor Pro

Indications for Use *(Describe)*
DreaMed Advisor Pro is a decision-support software intended for assisting healthcare professionals in the management of patients with Type 1 diabetes who:

•use insulin pumps as their insulin delivery therapy;
• monitor their glucose levels using CGM and/or self-management blood glucose meter;
• are above the age of 6 and under 65 years old; and
• use rapid acting U-100 insulin analogs in their pump.

DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing continuous glucose monitoring (CGM), self-monitoring blood glucose (SMBG) and pump data to generate recommendations for optimizing a patient's insulin pump settings for basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgement.

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

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	DreaMed Diabetes Ltd. 5 Mota Gur Street Petah Tikva 4952701 Israel
1. (b)	***Manufacturer Address:***	DreaMed Diabetes Ltd. 5 Mota Gur Street Petah Tikva 4952701 Israel
	Mfg. Phone:	Tel.: +972-52-3166684
	Contact Person:	Mr. Eran Atlas
	Date:	May 20th, 2019
2.	***Device & Classification Name:***	DreaMed Advisor Pro, which is an Insulin Pump Therapy Adjustment Calculator For Healthcare Professionals classified as Class 2 QCC, Regulation Number 21 CFR 862.1358
3.	***Predicate Device:***	Trade/Device Name: DreaMed Advisor Pro Regulation Number: 21 CFR 862.1358 Regulation Name: Insulin Therapy Adjustment Device Regulatory Class: Class II Product Code: QCC DEN170043
4.	***Description:***	DreaMed Advisor Pro is a software device that is designed to provide insulin therapy adjustment recommendations to physicians to assist in the management of diabetes for patients with Type 1 diabetes using an insulin pump, a continuous glucose monitoring (CGM) system and self-management blood glucose meter (SMBG). The DreaMed Advisor Pro gathers and analyzes information inputted through qualified Diabetes Management Systems (DMS), which collects biological input information from various diabetes devices. Diabetes device information required and used by DreaMed Advisor Pro includes glucose readings (either CGM sensor readings and/or capillary blood glucose measurements), insulin dosing logs, and meal data during daily routine care.

		Following data collection and analysis, the DreaMed Advisor Pro generates results containing summary data and recommendations for adjustments to the patient's insulin therapy parameters, including basal insulin delivery rate(s), insulin to carbohydrate ratio and correction factor (insulin sensitivity). DreaMed Advisor Pro may also advise behavioral changes. Results are sent to a qualified Diabetes Management Systems, which displays results to physicians and a report provided by DreaMed Diabetes. The physician can approve, reject or change the recommendations and issue the updated treatment plan to the patient.
5.	***Environment of Use:***	None
6.	***Intended Use and Indication for use:***	DreaMed Advisor Pro is a decision-support software intended for assisting healthcare professionals in the management of patients with Type 1 diabetes who: •use insulin pumps as their insulin delivery therapy; • monitor their glucose levels using CGM and/or self-management blood glucose meter; • are above the age of 6 and under 65 years old; and • use rapid acting U-100 insulin analogs in their pump. DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing continuous glucose monitoring (CGM), self-monitoring blood glucose (SMBG) and pump data to generate recommendations for optimizing a patient's insulin pump settings for basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgement.
7.	***Comparison of the indication for use***	With respect to the indication for use we conclude that the differences in the indication for use of new version of DreaMed Advisor Pro do not affect the safety and effectiveness of the device and do not alter the intended the use of the devices.
8.	***Comparison of Technological Characteristics:***	With respect to technology characteristics the new version of DreaMed Advisor Pro is substantially equivalent to its predicate device. DreaMed Diabetes believes that their device does not raise additional safety of efficacy concerns. At the end of this summary, a comparison table is provided.
9.	***Non-clinical tests***	DreaMed Advisor Pro was validated pursuant to the Major Level of Concern requirements. Design validation testing and human factors study results confirmed that the DreaMed Advisor Pro performs according to the stated intended use. The Human Factors validation was documented according to FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). Software evaluation consisted of functional testing performed pursuant to DreaMed's software test plan. All test results fell within the pre-determined specification parameters and acceptance criteria. Special controls were implemented and validated according to DreaMed software test plan.

In addition, DreaMed has performed retrospective tests between the predicate device and the subject device. Results show that the two devices present high level of agreement when comparing the recommendations of each version over similar data sets of patients. Thus, from the high rate of level of agreement we can conclude that if there is enough data with simulated-SMBG DreaMed Advisor Pro is making similar recommendations to pump settings as DreaMed Advisor Pro (DEN170043) would do. When there is not data enough data DreaMed Advisor Pro doesn't recommend to changes the pump settings. This is exactly the characteristics of DreaMed Advisor Pro (DEN170043) when there is not enough CGM data to make certain recommendation. Therefore, it can be concluded that DreaMed Advisor Pro is substantially equivalent to DreaMed Advisor Pro (DEN170043).

10. ***Clinical Tests:*** Additional retrospective clinical study were performed to evaluate physicians' strategies of adjustment of insulin pump settings based on glucometer and pump data alone for patients with type 1 diabetes and to compare results to automated recommendations given by the DreaMed Advisor Pro. The study involved 17 experts which reviewed data set of 15 patients. Recommendations were compared to examine the level of agreement between one expert to his colleague (total of 136 pairs) versus the level of agreement between DreaMed Advisor Pro recommendations and experts (total of 17 pairs). The study results show that the recommendations of the DreaMed Advisor Pro when is based on SMBG data alone were significantly as good as the recommendations of expert in the basal, CR and in the CF plan with regards to the direction of change. Therefore, the Advisor Pro recommendations could be considered similar to those given by Healthcare Professional who work at leading centers with a wealth of experience in the field of diabetes and who are especially familiar with diabetes technology devices

The following table compares these features and characteristics:

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device** **DreaMed Advisor Pro (subject device)**	**Predicate Device** **DreaMed Advisor Pro (DEN 170043)**	**Assessment of difference**
Product Code	QCC	QCC	Same
Intended use (the general purpose of the device or its function)	An Insulin pump therapy adjustment calculator for healthcare professionals, intended to recommend insulin pump therapy parameters adjustments (e.g. basal rates, insulin to carbohydrate ratios, insulin sensitivity factors) based on data from external devices, including continuous glucose monitors	An Insulin pump therapy adjustment calculator for healthcare professionals, intended to recommend insulin pump therapy parameters adjustments (e.g. basal rates, insulin to carbohydrate ratios, insulin sensitivity factors) based on data from external devices, including continuous glucose monitors	Same
Indication for use (the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended)	DreaMed Advisor Pro is a decision-support software intended for assisting healthcare professionals in the management of patients with Type 1 diabetes who: • use insulin pumps as their insulin delivery therapy; ***• monitor their glucose levels using CGM and/or self-management blood glucose meter*** • are above the age of 6 and under 65 years old; and • use rapid acting U-100 insulin analogs in their pump DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing continuous glucose monitoring (CGM), self-monitoring	DreaMed Advisor Pro is a decision-support software intended for assisting healthcare professionals in the management of patients with Type 1 diabetes who: • use insulin pumps as their insulin delivery therapy; ***• monitor their glucose levels using either of the following:*** ***o CGM, or*** ***o CGM and self-management blood glucose meter*** • are above the age of 6 and under 65 years old; and • use rapid acting U-100 insulin analogs in their pump DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing	Different (marked with BOLD)

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device**	**Predicate Device**	**Assessment of difference**
	DreaMed Advisor Pro (subject device)	**DreaMed Advisor Pro (DEN 170043)**	
	blood glucose (SMBG) and pump data to generate recommendations for optimizing a patient's insulin pump settings for basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgment.	continuous glucose monitoring (CGM), self-monitoring blood glucose (SMBG) and pump data to generate recommendations for optimizing a patient's insulin pump settings for basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgment.	
Data inputs types	Continuous glucose monitoring (CGM), self-monitoring blood glucose (SMBG) and pump data	Continuous glucose monitoring (CGM), self-monitoring blood glucose (SMBG) and pump data	Same
Timeframe over which data inputs must be collected	21 days	21 days	Same
Minimum number of data points required for accurate recommendations	Minimum of 12 valid days in order to perform analysis, where a valid day is defined as a day the consisted of: **Minimum glucose data per valid day:** • **At least 67% of CGM sensor readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings**	Minimum of 12 valid days in order to perform analysis, where a valid day is defined as a day the consisted of: **Minimum glucose data per valid day:** • **At least 67% of CGM sensor readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings**	Different (marked with BOLD)

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device** **DreaMed Advisor Pro (subject device)**	**Predicate Device** **DreaMed Advisor Pro (DEN 170043)**	**Assessment of difference**
	every 15 minutes at least 64 samples), OR • **At least 4 BG measurements a day that are separated from each other by a least 160 minutes.** Minimum insulin pump data per valid day: • At least 1 basal rate record • At least 1 bolus record In addition, insulin pump settings at analysis must be within the following acceptable range: • Basal rate - Each rate in the basal plan is within 0.025-3 u/h • Carbohydrate ratio - Each value in the CR plan is within 3-70gr/u • Correction Factor - Each value in the CF plan is within 10-280gr/u • Bolus calculator targets - Equal to or below 150 mg/dl	**every 15 minutes at least 64 samples)** Minimum insulin pump data per valid day: • At least 1 basal rate record • At least 1 bolus record In addition, insulin pump settings at analysis must be within the following acceptable range: • Basal rate - Each rate in the basal plan is within 0.025-3 u/h • Carbohydrate ratio - Each value in the CR plan is within 3-70gr/u • Correction Factor - Each value in the CF plan is within 10-280gr/u • Bolus calculator targets - Equal to or below 150 mg/dl	
Input data specifications, including accuracy requirements for continuous glucose monitors and other devices generating data inputs	• Blood glucose meters - All meters with regulatory approval (dependent on location: EU / US/ Rest of the World [ROW]) • Insulin pump - All insulin pumps with regulatory approval (dependent on location: EU /	• Blood glucose meters - All meters with regulatory approval (dependent on location: EU / US/ Rest of the World [ROW]) • Insulin pump - All insulin pumps with regulatory approval (dependent on location: EU /	Same

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device**	**Predicate Device**	**Assessment of difference**
	DreaMed Advisor Pro (subject device)	**DreaMed Advisor Pro (DEN 170043)**	
	US/ ROW), including those with low glucose suspend or predicted low glucose suspend features. • Continuous Glucose sensors – CGM which has received regulatory approval from authorities, where as part of this approval safety and efficacy data was shown to verify accuracy of the CGM below MARD of 15%.	US/ ROW), including those with low glucose suspend or predicted low glucose suspend features. • Continuous Glucose sensors – CGM which has received regulatory approval from authorities, where as part of this approval safety and efficacy data was shown to verify accuracy of the CGM below MARD of 15%.	
Device outputs and insulin therapy adjustment recommendations type	• Insulin therapy adjustment recommendations include basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient • Personal diabetes management tips	• Insulin therapy adjustment recommendations include basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient • Personal diabetes management tips	Same

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device**	**Predicate Device**	**Assessment of difference**
	DreaMed Advisor Pro (subject device)	**DreaMed Advisor Pro (DEN 170043)**	
Clinical validity of the device outputs and insulin therapy recommendations	The clinical validity of the device output was evaluated in a retrospective study versus experts in the field of diabetes	The clinical validity of the device output was evaluated in a retrospective study versus experts in the field of diabetes	Same
Means of data transmission to and from the device, including data integrity checks, accuracy checks, reliability checks, and security measures	Data is transmitted from DMS to Advisor device using SSL mechanism, JSON data structure. Integrity checks, accuracy checks, reliability checks are performed throughout the data transmission from the data system, to the algorithm and from the algorithm back to the data system	Data is transmitted from DMS to Advisor device using SSL mechanism, JSON data structure. Integrity checks, accuracy checks, reliability checks are performed throughout the data transmission from the data system, to the algorithm and from the algorithm back to the data system	Same
Usability characteristics	The device has a graphical user interface which presents to the healthcare professional the report of the Advisor. The healthcare professional can review, edit and share the recommendations with the patient. The healthcare professional can review the glucose/insulin data that was used to generate the Advisor recommendations. The graphical user interface was evaluated in HF/UE studies to ensure safety	The device has a graphical user interface which presents to the healthcare professional the report of the Advisor. The healthcare professional can review, edit and share the recommendations with the patient. The healthcare professional can review the glucose/insulin data that was used to generate the Advisor recommendations. The graphical user interface was evaluated in HF/UE studies to ensure safety	Same
Means to minimize the occurrence of dosing recommendation errors	• Advisor implements protective measures to ensure the reliability of the input data such	• Advisor implements protective measures to ensure the reliability of the input data such	Same

Table 2: Technological Characteristics Comparison			
Feature / Characteristic	**Subject Device**	**Predicate Device**	**Assessment of difference**
	DreaMed Advisor Pro (subject device)	**DreaMed Advisor Pro (DEN 170043)**	
	as filtering non-physiological glucose inputs, not considering rises in glucose which are attributed to specific behavior, correcting errors in clock shift between devices. • Advisor has limitations to the magnitude of the output to ensure safety	as filtering non-physiological glucose inputs, not considering rises in glucose which are attributed to specific behavior, correcting errors in clock shift between devices. • Advisor has limitations to the magnitude of the output to ensure safety	
Use of automated insulin dosing system with the device	Not allowed - part of the contraindication devices.	Not allowed - part of the contraindication devices.	Same
Identification of specific insulin formulations that have been demonstrated to be compatible with use of the device	Rapid acting U-100 insulin analogs	Rapid acting U-100 insulin analogs	Same
Principles of Operation	Algorithmic software device	Algorithmic software device	Same

Conclusion

DreaMed Diabetes believes that the changes as described in this 510(k) submission, do not present additional safety or effectiveness concerns for the *DreaMed Advisor Pro,* which is a modification of the legally marketed *DreaMed Advisor Pro (DEN170043)*. This is based upon the testing and validation data provided in this 510(k) notification. Accordingly, this should be sufficient for the FDA to determine the *DreaMed Advisor Pro* to be substantially equivalent to its predicate device because it has the same intended use and the same fundamental technology.