September 28, 2021

DreaMed Diabetes Ltd.
Inbal Beinglass Peled
5 Mota Gur St.
Petah Tikva, 4952701
Israel

Re: K210561
Trade/Device Name: Advisor Pro Platform
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QCC, NDC
Dated: February 22, 2021
Received: February 25, 2021

Dear Inbal Beinglass Peled:

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 -S

Kellie B. Kelm, Ph.D.
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210561

Device Name
Advisor Pro Platform

Indications for Use *(Describe)*

Advisor Pro Platform

The Advisor Pro Platform is intended for the management of diabetes by people with diabetes and their health care providers in order to report, log, track, share, monitor and review their data using the dedicated computer or mobile software. Advisor Pro Platform also enables communication between people with diabetes and their health care providers as well as among health care providers.

The Advisor Pro Platform enables the healthcare provider to use the Advisor Pro Algorithms for treatment recommendations as described below and prescribe the Advisor Pro Bolus Calculator for patient use.

Advisor Pro Algorithm

Advisor Pro Algorithm is a decision-support software intended for assisting healthcare professionals in the management of their patients with diabetes who monitor their glucose levels using continuous glucose monitor (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter; and use any of the following insulin types as their therapy to manage glucose levels via subcutaneous injections or continuous sub-cutaneous insulin infusion (CSII; insulin pump) reported either manually or automatically:

- Long Acting insulins (for injections only)
- Short acting insulins:
  - Rapid acting analogs (for injections and insulin pump according to manufacturer indications for use)
  - Regular human insulin (for injections only)

The Advisor Pro algorithm is intended to be used for patients with:

- Type 1 diabetes over the age of 6 using an insulin pump or subcutaneous insulin injections.
- Type 2 diabetes over the age of 10 who use subcutaneous insulin injections.

Advisor Pro Algorithm is indicated for use by healthcare professionals when analyzing CGM, SMBG and/or insulin delivery data to generate recommendations for optimizing a patient's insulin treatment plan for basal therapy and/or bolus therapy and/or glucose targets; without considering the full clinical status of a particular patient. Advisor Pro Algorithm does not replace clinical judgment.

Advisor Pro Bolus Calculator

The Advisor Pro Bolus Calculator, a component of the DreaMed Diary App, is a diabetes management tool for people with type 1 diabetes above the age of 6 and type 2 diabetes above the age of 10, who use subcutaneous insulin injections therapy (not for pump use). This tool can help calculate their rapid acting analogs for insulin bolus doses based on user-entered blood glucose and/or meal information.

The initial setup of the user's treatment plans, and bolus calculator settings must be performed by a healthcare provider.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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**
**DreaMed Advisor Pro Platform**

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

DreaMed Diabetes Ltd.
5 Mota Gur St.
Petah Tikva
4952701
Israel

Contact Person: Inbal Beinglass Peled
Email: inbal.peled@dreamed.ai
Phone: +972-52-3642760
Date Prepared: February 22, 2021

**Name of Device and Name/Address of Sponsor**

Advisor Pro Platform
DreaMed Diabetes Ltd.
5 Mota Gur Street
Petah Tikva
4952701 Israel

**Common or Usual Name**

Insulin Therapy Adjustment Device

**Classification**

Class II, 21 CFR 862.1358, Product Code: QCC

**Predicate Devices**

DreaMed Advisor Pro, K201476

Reference Device: Accu-Chek Connect Diabetes Management App, Roche Diabetes Care Inc., K150910

**Intended Use / Indications for Use**

Advisor Pro Platform
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The Advisor Pro Platform enables the healthcare provider to use the Advisor Pro Algorithms for treatment recommendations as described below and prescribe the Advisor Pro Bolus Calculator for patient use.

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The initial setup of the user's treatment plans, and bolus calculator settings must be performed by a healthcare provider.

**Device Description**

The Advisor Pro Platform is a software device that is designed to be a diabetes management platform. It includes the Advisor Pro Algorithm that provides insulin therapy adjustment recommendations to physicians to assist in the management of diabetes for patients with Type 1 diabetes using an insulin pump or multiple daily injections, a continuous glucose monitoring (CGM) system and/or self-management blood glucose meter (SMBG). The Advisor Pro Algorithm also provides insulin therapy adjustment recommendations to physicians to assist in the management of diabetes for patients with Type 2 diabetes on basal-bolus therapy via multiple daily injections (MDI), a continuous glucose monitoring (CGM) system and/or self-management blood glucose meter (SMBG).

The Advisor Pro Algorithm gathers and analyzes information inputted through the Diabetes Management Systems (DMS), which collects biological input information from various diabetes devices and data sources including the DreaMed Diary App. Diabetes device information

required and used by Advisor Pro Algorithm 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 Advisor Pro Algorithm 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) for pump patients and for MDI patients a daily injection plan including a basal plan and either a sliding scale or insulin to carbohydrate ratio and correction factor (insulin sensitivity) for bolus injections. Advisor Pro Algorithm may also advise on personalized diabetes management tips. Results are sent to the Diabetes Management System, which displays results to physicians and a report provided by the algorithm. The physician can approve, reject or change the recommendations and issue the updated treatment plan to the patient.

For MDI patients using rapid acting analogs for insulin bolus dose, the healthcare provider may prescribe the Advisor Pro Bolus Calculator which is integrated in the DreaMed Diary App to aid in calculating their bolus injections.

**Substantial Equivalence**

The Advisor Pro Platform is as safe and effective as the predicate devices. The Advisor Pro Platform has the same principles of operation as the predicate devices.

With respect to the technological characteristics, the difference in the specification for minimal BG required, the difference does not affect the safety and effectiveness of the device as the recommendations before and after the change ultimately remain the same and thus the devices are substantially equivalent.

With respect to the indication for use we conclude that the differences in the indication for use between the predicates in allowing HCPs to receive insulin therapy adjustment recommendations for their Type 1 and Type 2 MDI patients do not affect safety and effectiveness of the device. This is based on the risk analysis, the clinical evidence and the human factors testing which show that the device is safe and effective for this additional treatment population. The indications for use differences between the Advisor Pro Algorithm and its predicate devices raise no new issues of safety or effectiveness. Thus, the Advisor Pro Algorithm is substantially equivalent to its predicate device.

The Advisor Pro Bolus Calculator is substantially equivalent to the predicate device as it is has the same intended use and any minor differences related to technological characteristics such as: max bolus size and meal size type do not raise any new question of safety and effectiveness.

**Software**

Advisor Pro Platform was validated pursuant to the Major Level of Concern requirements.

Design validation testing results confirmed that the Advisor Pro Platform performs according to the stated intended use. 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.

**Human Factors**

Human factors testing was conducted with the intended user populations of patients and healthcare providers. The Human Factors validation was documented according to FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human factors, design, and labeling information provided in the submission confirm that the user interface has been adequately validated for use per the labeling.

**Clinical Evidence**

Additional retrospective clinical study was performed to evaluate physicians' strategies of adjustment of Type 1 and Type 2 MDI patients' basal-bolus therapy plan based on glucose and insulin injection data and to compare results to automated recommendations given by the Advisor Pro Algorithm. The study involved a data set of 17 Type 1 patients and 15 Type 2 patients and a total of 36 experts.

Recommendations were compared to examine the level of agreement between one expert to his colleague versus the level of agreement between Advisor Pro Algorithm recommendations and experts. The study results show that the recommendations of the Advisor Pro Algorithm Pro for MDI patients Type 1 and Type 2 were significantly as good as the recommendations of expert in the basal and bolus plans plan with regards to the overall level of agreement in the direction of change. Therefore, the Advisor Pro Algorithm 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.

**Conclusions**

DreaMed Diabetes believes that the changes as described in this 510(k) submission do not present additional safety or effectiveness concerns for the Advisor Pro Platform including the Advisor Pro Algorithm as well as the Advisor Pro Bolus Calculator and is substantially equivalent to the predicates cited.