August 28, 2020

DreaMed Diabetes Ltd
Inbal Beinglass Peled, Director RA/QA
5 Mota Gur St
Petah Tikva, 4952701
Israel

Re: K201476
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: June 3, 2020
Received: June 3, 2020

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,

Marianela Perez-Torres, Ph.D.
Acting Deputy 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201476

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 continuous glucose monitoring (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter;
• are above the age of 6; and
• use rapid acting U-100 insulin analogs in their pump
DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing CGM, 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
DreaMed Advisor Pro

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: August 28, 2020

Name of Device and Name/Address of Sponsor

DreaMed Advisor Pro
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, K191370

Intended Use / Indications 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 continuous glucose monitoring (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter;
- are above the age of 6; and
- use rapid acting U-100 insulin analogs in their pump

DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing CGM, 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.

Device 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.

Substantial Equivalence

The Advisor Pro is as safe and effective as the previously cleared Advisor Pro. The Advisor Pro has the same technological characteristics and principles of operation as the previously cleared Advisor Pro.

With respect to the indication for use we conclude that the differences in the indication for use between the previous and updated Advisor Pro in allowing patients over the age of 65 to use the device do not affect the safety and effectiveness of the device. This is because based on literature and feedback from clinicians, patients do not receive different insulin therapy management based on their age alone but rather it is based on their overall health and any such considerations are already included in the current labeling. Thus, physicians treating patients over the age of 65 who are otherwise healthy and meet all other indications, device specifications and are not contraindicated could use the device. Anyone else not falling under the indications, falling under the contraindications or not meeting device specifications would not be treated using the device. The indications for use differences between the Advisor Pro and its predicate devices raise no new issues of safety or effectiveness. Thus, the Advisor Pro is substantially equivalent to its predicate device.

Conclusions

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 (K191370).