June 12, 2018

Eran Atlas
DreaMed Diabetes, Ltd.
3 Shimshon St., Petah Tikva,
POB 3271, IL 4952701

Re: DEN170043
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: August 15, 2017
Received: August 17, 2017

Dear Mr. Atlas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the DreaMed Advisor Pro, a prescription device with the following 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 either of the following:
>   - CGM, or
>   - 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 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the DreaMed Advisor Pro, and substantially equivalent devices of this generic type, into Class II under the generic name "Insulin Therapy Adjustment Device."

FDA identifies this generic type of device as:

> **Insulin Therapy Adjustment Device.** An insulin therapy adjustment device is a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 17, 2017, FDA received your De Novo requesting classification of the DreaMed Advisor Pro. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the DreaMed Advisor Pro into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the DreaMed Advisor Pro can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Required Mitigations
Erroneous or extreme changes in insulin dosing recommendations may cause hypoglycemia or hyperglycemia.	General Controls and special controls (1), (2), and (3)
Incorrect interpretation of results may lead to inappropriate clinical decision making.	General Controls and special controls (1), and (3)
Incorrect understanding of appropriate device use may lead to inappropriate treatment decisions.	General Controls and special controls (1), (2), and (3)
Patient harm due to insecure transmission of data.	General Controls and special control (1)
Data corruption may lead to inappropriate treatment recommendations.	General Controls and special control (1)

In combination with the general controls of the FD&C Act, the insulin therapy adjustment device is subject to the following special controls:

1. Design verification and validation must include the following:
    (i) A complete description of the required data inputs, including timeframe over which data inputs must be collected and number of data points required for accurate recommendations.
    (ii) A complete description of the types of device outputs and insulin therapy adjustment recommendations, including how the recommendations are generated.
    (iii) Robust data demonstrating the clinical validity of the device outputs and insulin therapy recommendations.
    (iv) A robust assessment of all input data specifications, including accuracy requirements for continuous glucose monitors and other devices generating data inputs, to ensure accurate and reliable therapy adjustment recommendations. This assessment must include adequate clinical justification for each specification.
    (v) A detailed strategy to ensure secure and reliable means of data transmission to and from the device, including data integrity checks, accuracy checks, reliability checks, and security measures.
    (vi) Robust data demonstrating that users can understand and appropriately interpret recommendations generated by the device.
    (vii) An appropriate mitigation strategy to minimize the occurrence of dosing recommendation errors, and to mitigate the risk to patients of any residual dosing recommendation errors to a clinically acceptable level.
2. The device must not be intended for use in implementing automated insulin dosing.
3. Your 809.10(b) labeling must include:
    (i) The identification of specific insulin formulations that have been demonstrated to be compatible with use of the device.
    (ii) A detailed description of the specifications of compatible devices that provide acceptable input data (e.g., continuous glucose monitors, insulin pumps) used to provide accurate and reliable therapy adjustment recommendations.
    (iii) A detailed description of all types of required data (inputs) and dosing recommendations (outputs) that are provided by the device.
    (iv) A description of device limitations, and instructions to prevent possible disruption of accurate therapy adjustment recommendations (e.g., time zone changes due to travel).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a

premarket notification containing information on the Insulin Therapy Adjustment Device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Naomi Schwartz at 301-796-2645.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
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