October 3, 2023

DreaMed Diabetes Ltd.
Eran Atlas, CEO
14 Kaplan St, POB 3271
Petah Tikva, 4952701
Israel

Re: K232722
Trade/Device Name: endo.digital Platform
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QCC, NDC
Dated: September 5, 2023
Received: September 5, 2023

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 (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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232722

Device Name
endo.digital Platform

Indications for Use *(Describe)*

endo.digital Platform

endo.digital Platform is intended for the management of diabetes by people with diabetes and their healthcare providers in order to report, upload, log, track, share, monitor and review their data using web and mobile applications. endo.digital Platform also enables communication between people with diabetes and their healthcare providers as well as among healthcare providers.

endo.digital Platform enables the healthcare provider to use endo.digital Algorithm for treatment recommendations as described below and prescribe endo.digital Bolus Calculator for patient use.

endo.digital Algorithm

endo.digital 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)

endo.digital 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.

endo.digital 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. endo.digital Algorithm does not replace clinical judgement.

endo.digital Bolus Calculator

endo.digital 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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dreamed

510(k) SUMMARY
endo.digital Platform

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

DreaMed Diabetes Ltd.
14 Kaplan St.
Petah Tikva
4952701
Israel

Contact Person: eran.atlas
Email: eran.atlas@dreamed.ai
Phone: +972-52-3166684
Date Prepared: August 29,2023

510(k) Number

K232722

Name of Device and Name/Address of Sponsor

endo.digital Platform (combined with endo.digital Algorithm for insulin injections version 02.05.xx, endo.digital Algorithm for insulin pumps version 01.09.xx, endo.digital Algorithm Server version 02.01.xx)
DreaMed Diabetes Ltd.
14 Kaplan St
Petah Tikva
4952701 Israel

Common or Usual Name

Insulin Therapy Adjustment Device

Calculator, Drug Dose

Classification

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

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

Predicate Devices

Advisor Pro Platform, K210561

Intended Use / Indications for 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

endo.digital Platform is a software device that is designed to be a diabetes management platform. It includes endo.digital 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). endo.digital 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). endo.digital Algorithm gathers and analyzes information inputted

through the Diabetes Management Systems (DMS), which collect biological input information from various diabetes devices and data sources including the DreaMed Diary App. Diabetes device information required and used by endo.digital 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 endo.digital 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 (which can include Fixed Meal and Meal Estimation plans) or insulin to carbohydrate ratio and correction factor (insulin sensitivity) for bolus injections. endo.digital 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 endo.digital Bolus Calculator which is integrated in the DreaMed Diary App to aid in calculating their bolus injections.

Substantial Equivalence

endo.digital Platform has the same intended use as the previously cleared DreaMed Advisor Pro. In addition, endo.digital Platform has very similar indications, technological characteristics, and principles of operation as its predicate. The indications for use difference between the subject device and its predicate device, which consists of the additional device capability wherein data can be uploaded directly to the device, raises no new issues of safety or effectiveness. Similarly, the only difference in the device's output are the additional options for insulin therapy adjustment recommendations, which now include plans for Fixed Meal with sliding scale correction and for Meal Estimation with sliding scale correction. As the cleared predicate device already implemented the technological characteristics of analyzing insulin bolus plans that include separate settings for the meal portion of the bolus and the correction portion of the bolus in some treatment plans, the addition of these new treatment plans does not raise any new risks.

Therefore, although there are minor differences between endo.digital Platform and its predicate, those differences do not raise new questions of safety or efficacy. Furthermore, software performance data demonstrates that endo.digital Platform is as safe and effective as the predicate device. Thus, endo.digital Platform is substantially equivalent.

Software

endo.digital Platform was validated pursuant to the Major Level of Concern requirements. Design validation testing results confirmed that endo.digital 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.

Conclusions

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