510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K210561

B Applicant

DreaMed Diabetes Ltd.

C Proprietary and Established Names

Advisor Pro Platform

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QCC	Class II	21 CFR 862.1358 - Insulin Therapy Adjustment Device	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to a previously cleared device to allow patients on Multiple Daily Injection (MDI) therapy to use the Advisor Pro Algorithm, and to add a bolus dose calculator for users of rapid acting insulin analogs.

B Type of Test:

Insulin Therapy Adjustment Device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Advisor Pro Algorithm:

For in vitro diagnostic use only

Advisor Pro algorithm is not intended to send recommendations directly to patients without initially being reviewed and approved by a certified HCP who considers the entire clinical status of the patient.

Advisor Pro algorithm is not recommended for patients that change their concomitant glucose-lowering therapies or alter their current therapy dose while using the Advisor Pro Algorithm. Since Advisor Pro algorithm only analyzes the insulin dosing history data and assumes all other elements that affect glucose levels are stable, the effect of changing or altering the dose of other glucose-lowering therapies will not be taken into consideration by Advisor Pro algorithm. This could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.Advisor Pro algorithm is not recommended for pregnant women. Advisor Pro has not been tested in this population.

Advisor Pro algorithm is not intended for use with patients who use automated insulin dosing (AID) systems (e.g., "closed-loop", "artificial pancreas"). Advisor Pro algorithm hasn't been tested with these devices. Advisor Pro algorithm cannot identify the pump model or operating mode, and although Advisor Pro algorithm has some design mitigations to help detect when AID systems are used in closed loop mode and will usually prevent the system from providing recommendations for pump parameter changes, it cannot detect closed loop insulin delivery 100% of the time. Therefore, pay attention to pump information and the pump's operating mode and do not accept Advisor Pro recommendations if the user was using the AID system in closed loop mode.

Advisor Pro algorithm is not intended for use with patients who use insulin(s) other than the types indicated above. Advisor Pro algorithm hasn't been tested with other types of insulins. Using Advisor Pro algorithm with other types of insulin may lead to potential harm.

Advisor Pro algorithm is not recommended for patients who have changed their insulin type within the last 21 days. Since Advisor Pro algorithm only analyzes the current plan, the effect of changing the insulin type during period for analysis is not taken into consideration. This could

result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.

Advisor Pro algorithm is not intended for use with patients treated with intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy. Since Advisor Pro algorithm analyzes the insulin dosing history, it assumes a certain insulin delivery methodology as per the physician settings of the patient profile. Using Advisor Pro algorithm in the above manner could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.

IV Device/System Characteristics:

A 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, the Advisor Pro Bolus Calculator and the DreaMed Diary App. The Advisor Pro Algorithm provides insulin therapy adjustment recommendations to healthcare professionals for the management of their patients with diabetes (Type 1 or Type 2) who monitor their glucose levels using continuous glucose monitor (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter and use insulin to manage glucose levels via subcutaneous injections (multiple daily injections (MDI)) or continuous sub-cutaneous insulin infusion (CSII, insulin pump) with dosing data reported either manually or automatically. The DreaMed Diary App allows those people with diabetes who administer Multiple Daily Injections (MDIs) of insulin to easily log and track blood glucose levels, insulin delivery and physical activity, as well as carb and meal information, providing that information as input to the DreaMed Advisor Pro Platform used by their HCP. The Advisor Bolus Calculator is hosted within the Diary App.

The Advisor Pro Algorithm gathers and analyzes information inputted through the Diabetes Management Systems (DMS), which collects 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 a daily injection plan for MDI patients including a basal plan as well as 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 insulin to carbohydrate ratio and correction factor (insulin sensitivity) for bolus injections the healthcare provider may prescribe the Advisor Bolus Calculator which is integrated in the DreaMed Diary App to aid in calculating their bolus injections.

B Instrument Description Information:

1. Instrument Name:
   Advisor Pro Platform

2. Specimen Identification:
   Not applicable.

3. Specimen Sampling and Handling:
   Not applicable.

4. Calibration:
   Not applicable.

5. Quality Control:
   Not applicable.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
DreaMed Advisor Pro

B Predicate 510(k) Number(s):
K201476

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210561	K201476
Device Trade Name	Advisor Pro Platform	DreaMed Advisor Pro
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Decision-support for assisting healthcare professionals in the management of insulin pump therapy for 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 (SMBG) meter; and • use rapid acting U-100 insulin analogs in their pump
Timeframe over which data inputs must be collected	Same	21 days
Principles of Operation	Algorithmic software device (Advisor Pro Algorithm) and insulin dose calculator based on user-entered data (Advisor Pro Bolus Calculator).	Algorithmic software device
Glucose Data Sources	Algorithm: - Continuous glucose monitoring system data, or - Continuous glucose monitoring system data and self-monitoring blood glucose meter values, or - Self-monitoring blood glucose meter values (at least three per day, spaced at least 210 minutes apart) Bolus Dose Calculator: - user-entered blood glucose	Algorithm: - Continuous glucose monitoring data, or - Continuous glucose monitoring data and self-monitoring blood glucose meter values, or - Self-monitoring blood glucose meter values (at least four per day, spaced at least 160 minutes apart)
Contraindications for Automated Insulin Dosing Systems	same	- This device is not intended for use with patients who use automated insulin dosing systems.
General Device Characteristic Differences		
Insulin Therapy Adjustment Recommendation Types	Same outputs. For pump and MDI users.	Insulin therapy adjustment recommendations including basal rate, carbohydrate ratio (CR), correction factors (CF), and personal diabetes management tips. For pump users only.

Bolus Calculator	Yes, for MDI users only	Not available
Age Range of Intended Users	Intended to be used for patients with: - Type 1 diabetes over the age of 6 - Type 2 diabetes over the age of 10	Intended to be used for patients with Type 1 diabetes above the age of 6

VI Standards/Guidance Documents Referenced:

21 CFR 862.1358 (Special controls established under DEN170043)

ISO 14971:2007; Medical Devices – Application of Risk Management to Medical Devices

ISO 15223-1:2016; Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements

IEC 62304:2006 – Medical Devices Software – Software Lifecycle Processes

IEC 62366-1:2015 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
IEC 60601-1-6:2010; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Not Applicable.

2. Linearity:
   Not Applicable.

3. Analytical Specificity/Interference:
   Not Applicable.

4. Accuracy (Instrument):
   Not Applicable.

5. Carry-Over:
   Not Applicable.

B Other Supportive Instrument Performance Characteristics Data:

The sponsor assessed the clinical impact of the design modifications compared to the predicate, and performed a non-interventional expert survey to evaluate the use of the Advisor Pro algorithm for MDI users with Type 1 and Type 2 diabetes. Results from these assessments support that the Advisor Pro Platform, with the modified Advisor Pro Algorithm and the new Advisor Pro Bolus Calculator, is substantially equivalent to the predicate.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.