

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY**

**I Background Information:**

**A 510(k) Number**

K191370

**B Applicant**

DreaMed Diabetes Ltd

**C Proprietary and Established Names**

DreaMed Advisor Pro

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
QCC	Class II	21 CFR 862.1358 - Insulin pump therapy adjustment calculator for healthcare professionals	CH - Clinical Chemistry

**II Submission/Device Overview:**

**A Purpose for Submission:**

Modification to a previously cleared device to allow analysis of either continuous glucose monitor data or self-monitoring blood glucose meter data.

**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:**

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 CGM and/or 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.

#### **C Special Conditions for Use Statement(s):**

- For Prescription Use Only
- For in vitro diagnostic use only
- This device is not intended to send recommendations directly to patients without initially being reviewed and approved by a healthcare professional (HCP).
- This device cannot generate recommendations for patients who are unwilling or unable to use a CGM.
- This device is not intended for use with patients who use automated insulin dosing systems (e.g., "closed-loop", "artificial pancreas").
- This device is not intended for use with patients who use insulin(s) other than U-100. The Advisor Pro is designed to consider the pharmacodynamics and pharmacokinetics of U-100 insulin only. Using Advisor Pro with other types of insulin may lead to patient harm.
- This device is not intended for use for patients treated with insulin injections, intravenous (IV) insulin, or a combination of insulin injections and/or IV insulin and insulin pump therapy. Since Advisor Pro analyzes the insulin dosing history from the insulin pump, it will be blind to insulin delivered by injections and/or IV insulin. This could result to a false conclusion about the changes to the patient's insulin pump settings and may lead to patient harm.
- This device is not intended for patients using other concomitant non-insulin glucose lowering therapies. Since the Advisor Pro analyzes the insulin dosing history from the insulin pump, reducing glucose levels by other means will not be taken into consideration by Advisor Pro.

This could result to a false conclusion about the changes to the patient's insulin pump settings and may lead to patient harm.

- This device is not intended for use with patients under the age of 6 or above the age of 65.
- This device is not intended for use in pregnant women.
- DreaMed Advisor Pro is not recommended for patients who are taking medications that might affect CGM/SMBG values, such as acetaminophen. Please refer to the warnings and contraindications of the patient's CGM/SMBG to determine whether said medications may falsely raise glucose readings of the sensor. The level of inaccuracy depends on the amount of said medication active in the patient's body and may be different for each person. Using Advisor Pro in these cases may lead to the potential harm.

#### **IV Device/System Characteristics:**

##### **A 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, and a continuous glucose monitoring (CGM) system and/or self-monitoring blood glucose (SMBG) system.

The DreaMed Advisor Pro gathers and analyzes information inputted through qualified 3rd party Diabetes Management Systems (DMS), which collect biological input information from insulin pumps, glucose meters, and continuous glucose monitoring systems. 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 a patient's insulin pump therapy parameters, including: basal insulin delivery rate(s), insulin to carbohydrate ratio, correction factor (insulin sensitivity), active insulin time and glucose targets. DreaMed Advisor Pro may also advise behavioral changes, such as reminders to change infusion sets every 2-3 days, to use current blood glucose information when calculating a bolus, and about the timing of meal boluses to avoid hyperglycemia. Results are sent to a qualified 3rd party Diabetes Management System, 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.

**B Instrument Description Information:**

<b>Modes of Operation</b>	<b>Yes</b>	<b>No</b>
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Software</b>		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

1. Instrument Name:  
DreaMed Advisor Pro
2. Specimen Identification:  
Not Applicable.
3. Specimen Sampling and Handling:  
Not Applicable.
4. Calibration:  
Not Applicable.
5. Quality Control:  
Not Applicable.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**  
DreaMed Advisor Pro

**B Predicate 510(k) Number(s):**  
DEN170043

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K191370</u>	<u>DEN170043</u>
Device Trade Name	<b>DreaMed Advisor Pro</b>	<b>DreaMed Advisor Pro</b>
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	Decision-support for assisting healthcare professionals in the management of insulin pump therapy for patients with Type 1 diabetes.	Decision-support for assisting healthcare professionals in the management of insulin pump therapy for patients with Type 1 diabetes.
Timeframe over which data inputs must be collected	21 days	21 days
Device outputs and insulin therapy adjustment recommendations type	Insulin therapy adjustment recommendations including basal rate, carbohydrate ratio (CR), correction factors (CF), and personal diabetes management tips.	Insulin therapy adjustment recommendations including basal rate, carbohydrate ratio (CR), correction factors (CF), and personal diabetes management tips.
Principles of Operation	Algorithmic software device	Algorithmic software device
<b>General Device Characteristic Differences</b>		
Glucose Data Sources	<ul style="list-style-type: none"> <li>- Continuous glucose monitor data, or</li> <li>- Continuous glucose monitor data and self-monitoring blood glucose meter values, or</li> <li>- Self-monitoring blood glucose meter values (at least four per day, spaced at least 160 minutes apart)</li> </ul>	<ul style="list-style-type: none"> <li>- Continuous glucose monitor data, or</li> <li>- Continuous glucose monitor data and self-monitoring blood glucose meter values</li> </ul>

## **VI Standards/Guidance Documents Referenced:**

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

ISO 14155 - Clinical Investigation Of Medical Devices For Human Subjects - Good Clinical Practice

## **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:**

#### Clinical Performance:

One study was conducted to evaluate the DreaMed Advisor Pro in the clinical use setting. The study of 15 health care providers compared differences in the use of DreaMed Advisor Pro between expert endocrinologists and the DreaMed Advisor Pro when only self-monitoring blood glucose (SMBG) data and insulin pump data were used. No continuous glucose monitor data was used for this study.

The study was an expert diabetes physician survey, conducted at centers in Croatia, Spain, Finland, Serbia, Italy, Greece, Belgium, South Africa, Czech Republic, United Arab Emirates and Israel, with a total of 17 physicians participating. Uploads of 15 patients (all with Type 1 Diabetes utilizing an insulin pump) including data of 3 weeks of SMBG and insulin pump data were assessed. Each of the 17 experts received 15 anonymized PDF files with patient data and general information about the patient including the patient's gender, age, HbA1c, weight, height and BMI as well as details about the current pump settings of the patient (i.e. basal rate plan, carbohydrates to insulin ratio plan (CR), correction factor plan (CF), bolus calculator glucose targets and active insulin time). Each expert was asked to provide her/his proposed recommended changes to insulin pump settings as well as state if any behavioral or lifestyle changes are recommended. All recommendations were recorded in a designated form provided to the expert. The results were compared to the Advisor Pro automated recommendations. The recommendations from the physicians at each site were also compared. The study results indicate that the recommendations of the DreaMed Advisor Pro were generally similar to the recommendations of expert physicians with respect to the basal rate as well as the carbohydrate ratio (CR) and correction factor (CF).

## **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.