510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K201476

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 Therapy Adjustment Device	Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to a previously cleared device to update the indications for use allowing patients over 65 years old to use the device.

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 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.

C Special Conditions for Use Statement(s):

- Rx - 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 is not intended for use with patients who use automated insulin dosing systems. (e.g., "closed-loop", "artificial pancreas", see labeling for a list of the contraindicated devices). Advisor Pro hasn't been tested with these devices. Advisor Pro cannot identify the pump model or operating mode, and although Advisor Pro 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.
- This device is not intended for use with patients who use insulin(s) other than U-100. Advisor Pro hasn't been tested with other types of insulins and is designed to consider the pharmacodynamics and pharmacokinetics of U-100 insulin only. Using Advisor Pro with other types of insulin may lead to potential harm.
- This device is not intended for use with 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 potential harm.
- This device is not intended for patients using other concomitant glucose lowering therapies. Since Advisor Pro analyze 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 potential harm.

- This device is not recommended for pregnant women. Advisor Pro hasn't been tested in this population.
- This device is not recommended for patients who are taking medications that might affect CGM/SMBG values. Please refer to the warnings and contraindications of the patient's CGM/ blood glucose meter to determine whether said medications may falsely raise glucose readings. 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 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 third 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 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 third 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:

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):
K191370

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201476	K191370
Device Trade Name	DreaMed Advisor Pro	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

Device & Predicate Device(s):	K201476	K191370
Device outputs and insulin therapy adjustment recommendations type	Same	Insulin therapy adjustment recommendations including basal rate, carbohydrate ratio (CR), correction factors (CF), and personal diabetes management tips.
Principles of Operation	Same	Algorithmic software device
Glucose Data Sources	Same	- Continuous glucose monitor data, or - Continuous glucose monitor 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		
Age Range of Intended Users	above the age of 6	above the age of 6 and under 65 years old

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

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:

A Clinical Impact Assessment for removing the upper age limit of 65 years old was provided in the submission and found to be acceptable.

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.