510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K203772

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod 5 SmartBolus Calculator

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QRX	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:

New device

B Type of Test:

Continuous Glucose Monitor Informed Insulin Dose Calculator

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Omnipod 5 SmartBolus Calculator is software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose reading (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value. The Omnipod 5 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

This device resides in the Omnipod 5 App and requires the App to function

The Omnipod 5 SmartBolus works with the following rapid-acting U-100 insulins. : NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro).

IV Device/System Characteristics:

A Device Description:

The Omnipod 5 SmartBolus Calculator is a software device that resides in the Omnipod 5 App. It requires input parameters and settings from the SmartAdjust Technology, an interoperable automated glycemic (iAGC) and glucose values from a compatible integrated continuous glucose monitoring system (iCGM) or blood glucose (BG) values from a blood glucose meter to calculate suggested insulin bolus doses. The Omnipod 5 SmartBolus Calculator can be used in both open-loop (manual mode) and closed-loop (automated mode). When used with a compatible iCGM, the Omnipod 5 SmartBolus Calculator can use the sensor glucose values and trend information to calculate a suggested bolus dose. When the Omnipod 5 SmartBolus Calculator is used with manually entered BG readings it suggests a bolus dose based on the same calculations as the currently cleared Omnipod DASH Insulin Management System bolus calculator (K180045, K192659).

B Instrument Description Information:

1. Instrument Name:
   Omnipod 5 SmartBolus Calculator

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):
K201476

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203772	K201476
Device Trade Name	Omnipod 5 SmartBolus Calculator	DreaMed Advisor Pro
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Software intended for the management of diabetes
Principle of operation	Same	Algorithmic software device
Age Range of Intended Users	Same	6 years and older
Glucose Data Sources	Same	Sensor glucose data from a compatible integrated continuous glucose monitor (iCGM) and/or self-monitoring blood glucose (SMBG) meter values
General Device Characteristic Differences		
Device Outputs	The Omnipod 5 SmartBolus Calculator calculates a suggested bolus dose output and calculates the insulin-on-board.	Insulin therapy adjustment recommendations including basal rate, carbohydrate ratio (CR), correction factors

		(CF), and personal diabetes management tips.
Timeframe over which data inputs must be collected	5 minutes	21 days

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1358 (Special controls established under DEN170043)
- IEC 62366:2015; Medical Devices – Park 1: Application of Usability Engineering
- HE75:2009, Human Factors Engineering – Design of Medical Devices
- ISO 14971:2007; Medical devices – Application of Risk Management to Medical Devices
- IEC 62304 Ed. 1.1 2015; Medical device software – Software life cycle processes
- FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005
- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

This is a software only device for insulin bolus dose calculation. The following analytical performance characteristics are not applicable.

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:

Summary of Clinical Testing:

A single-arm, multicenter, prospective clinical study was conducted to evaluate the Omnipod 5 SmartBolus Calculator in patients with type 1 diabetes during Manual Mode operation. The study enrolled 25 evaluable subjects aged 6-70 years across 3 clinical sites, and consisted of two 7-day outpatient phases of Omnipod 5 use:

- Phase 1: 7 days of Omnipod 5 use in Manual Mode without a connected CGM using manual entry of BG values to deliver boluses, followed by;

- Phase 2: 7 days of Omnipod 5 use in Manual Mode with a connected CGM using the CGM-informed bolus calculator to deliver boluses.

The primary objective of the study was to evaluate the safety of the CGM-informed bolus calculator using glucose metrics of percentage of time < 70 mg/dL and percentage of time > 180 mg/dL during the 4-hour post bolus period from Phase 1 as compared to Phase 2. Data from the clinical study is presented in the tables below. In the 25 subjects enrolled in the combined age cohort of 6.0-70.0 years, there were zero (0) deaths and zero (0) unanticipated adverse device effects (UADE) reported. One (1) serious adverse event (SAE) was reported that occurred in the aged 18.0-70.0 years cohort and was indicated as not related to the study procedures or study device. There were no non-serious adverse events reported.

Comparison of glycemic measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours after any bolus (N=25)

Percent time in glucose range as measured by CGM	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70-180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 300 mg/dL	2.0% (2.6)	2.6% (3.7)	0.6%

In Silico Testing: Simulations of possible input and output combinations were run to supplement information collected in the clinical study. These simulations evaluated additional types and/or ranges of variables in order to assess that potential edge cases (including physiologically improbable edge cases) will produce either a safe output (e.g., bolus recommendation), or an error alerting the user to an unsafe condition.

Human Factors:
The Omnipod 5 SmartBolus Calculator is a component of the Omnipod 5 System. Human Factors validation study was conducted on the Omnipod 5 System as a whole and described in the Decision Summary for K203774.

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.