510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K222239

B Applicant

Insulet Corporation

C Proprietary and Established Names

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:

Modification to a cleared device to expand the age indication (from ≥6 years old to ≥2 years old)

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 SmartBolus Calculator is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (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 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 SmartBolus Calculator 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 SmartBolus Calculator is a software device that resides in the Omnipod 5 App.
It requires input parameters and settings from the SmartAdjust™ Technology, a glycemic controller (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 SmartBolus Calculator can be used in both open-loop (manual mode) and closed-loop (automated mode). When used with a compatible iCGM, the SmartBolus Calculator can use the sensor glucose values and trend information to calculate a suggested bolus dose. When the 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:
   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):
Omnipod 5 SmartBolus Calculator

B Predicate 510(k) Number(s):
K203772

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222239	K203772
Device Trade Name	SmartBolus Calculator	OmniPod 5 SmartBolus Calculator
General Device Characteristic Similarities		
Indications For Use	The SmartBolus Calculator is software intended for the management of diabetes in persons requiring rapid-acting U-100 insulin. The SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (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 SmartBolus Calculator is intended for single patient, home	Same

	use and requires a prescription.	
General Device Characteristic Differences		
User Age	Ages 2 and older	Persons aged 6 and older

VI Standards/Guidance Documents Referenced:

- FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" dated October 25, 2017
- FDA Guidance "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" dated October 25, 2017
- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016
- ANSI AAMI IEC 62366-1:2015 – Medical Devices – Part 1: Application of Usability Engineering
- ANSI AAMI HE75:2009/(R)2018 – Human Factors Engineering – Design of Medical Devices
- ANSI AAMI ISO 14971:2019 – Medical devices – Application of Risk Management to Medical Devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The SmartBolus Calculator is a software-only device, therefore 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:

1. Clinical Testing:

CGM-Informed Bolus Calculator Study: Preschool Cohort

A single-arm, multicenter, prospective clinical study was conducted to evaluate the performance of the SmartBolus Calculator in patients with type 1 diabetes during Manual Mode (open-loop) operation. The study enrolled 5 evaluable subjects aged 2.0-5.9 years old across two 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
- Phase 2: 7 days of Omnipod 5 use in Manual Mode with a connected CGM using the SmartBolus 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 2 as compared to Phase 1. Data from the clinical study is presented in the table below.

There were no deaths, unanticipated adverse device effects (UADE) or serious adverse events (SAE) reported in this study. One (1) non-serious adverse event of prolonged hyperglycemia was reported which resolved after a Pod change with appropriate subcutaneous insulin coverage during the transition and appeared likely related to an infusion site issue rather than the SmartBolus calculator itself.

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=5)

Percent time in glucose range as measured by CGM	Standard SmartBolus Calculator (Phase 1)	CGM-Informed SmartBolus Calculator (Phase 2)	Change*
70-180 mg/dL	59.6 (7.1)	62.8 (15.5)	3.15 (16.72)
<70 mg/dL	5.16 (4.99)	4.03 (3.28)	-1.13 (4.09)
<54 mg/dL	1.47 (1.88)	0.81 (0.91)	-0.66 (1.39)
>180 mg/dL	35.2 (10.3)	33.2 (18.5)	-2.03 (18.72)
≥250 mg/dL	9.4 (5.7)	7.9 (6.4)	-1.55 (5.95)
≥300 mg/dL	2.33 (2.69)	1.99 (2.05)	-0.34 (1.83)

Results presented as average (standard deviation)
**Change is calculated as per-subject time in specified glycemic range during Phase 2 minus per-subject time in specified glycemic range during Phase 1.*

2. 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 different scenarios (including different bolus timing and miscalculated carbohydrate content) do not affect safety of the device in the intended user population.

3. Human Factors Testing:

The SmartBolus Calculator is a component of the Omnipod 5 System. Human factors validation testing was conducted with the Omnipod 5 App installed on a compatible mobile device. Human Factors validation study on the Omnipod 5 System as a whole was performed with 16 representative participants (i.e., caregivers of children 2-5.9 years old) and described in the Decision Summary for K220394.

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.