U.S. FOOD & DRUG ADMINISTRATION

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I   Background Information:

A   510(k) Number

K231824

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

E   Purpose for Submission:

Modifications to the device to add compatibility with the iOS version of the Omnipod 5 App component of the Omnipod 5 ACE Pump.

II   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).

III   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^{TM} 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).

IV   Substantial Equivalence Information:

A   Predicate Device Name(s):

SmartBolus Calculator

B   Predicate 510(k) Number(s):

K222239

C   Comparison with Predicate(s):

Device & Predicate Device(s):	K231824	K222239
Device Trade Name	SmartBolus Calculator	SmartBolus Calculator
General Device Characteristic Similarities		
Intended Use/Indications For Use	The SmartBolus Calculator is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100	Same

	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.	
General Device Characteristic Differences		
Omnipod 5 App Operating System	iOS and Android Operating System	Android Operating System

V   Standards/Guidance Documents Referenced:

ANSI AAMI ISO 14971:2019 Medical devices – Application of Risk Management to Medical Devices

IEC 62304:2015-05 Medical devices Software – (Software life cycle processes)

VI   Performance Characteristics:

A.   Analytical Performance

The SmartBolus Calculator is a software-only device, and therefore analytical performance characteristics are not applicable.

B.   Other Supportive Instrument Performance Characteristics Data

1. Human Factors:
   The SmartBolus Calculator is a component of the Omnipod 5 System. Human factors validation testing was conducted with the Omnipod 5 App (iOS) installed on a compatible mobile device. Human Factors validation study on the Omnipod 5 System as a whole was performed with 60 representative participants and is described in the Decision Summary for K231826.

2. Software:
Detailed information on software of the device was reviewed and found to be acceptable.

VII   Proposed Labeling:

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

VIII   Conclusion:

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