510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K232741

B Applicant

Insulet Corporation

C Proprietary and Established Names

SmartAdjust™ technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	Class II	21 CFR 862.1356 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry

E Purpose for Submission:

To update the performance specifications for connected integrated continuous glucose monitors (iCGM) in accordance with 21 CFR 862.1356(1)(iv).

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. SmartAdjust™ technology is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older. SmartAdjust™ technology is intended for single patient use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- SmartAdjust™ technology should not be used by anyone under the age of 2 years old.
- SmartAdjust™ technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.
- Do not use SmartAdjust™ technology in pregnant women, critically ill patients, and those on dialysis. The safety of the SmartAdjust™ technology has not been evaluated in these populations.
- Do not use SmartAdjust™ technology if you are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia.
- Do not use SmartAdjust™ technology if you do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders.
- SmartAdjust™ technology used with the Omnipod 5 System is designed to use rapid-acting U- 100 insulins. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro) for use up to 72 hours (3 days). Before using a different insulin with the Omnipod 5 System, check the insulin drug label and consult your healthcare provider. Refer to the insulin labeling and follow your healthcare provider's directions for how often to replace the Pod.
- SmartAdjust™ technology used with the Omnipod 5 System relies on accurate, current CGM values to determine your insulin needs. Always make sure you are using the CGM per manufacturer's instructions and do not extend the sensor wear beyond the recommended duration.
- Do NOT attempt to use the SmartAdjust™ technology with the Omnipod 5 System before you receive training. Inadequate training could put your health and safety at risk.
- Device components used with the SmartAdjust™ technology including the pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomoraphy (CT) scan, or diathermy treatment. In addition, the SmartAdjust™ Controller and smartphone should be placed outside of the precedure room. Exposure to MRI, CT, or diathery treatment can damage the components.

III Device Description:

SmartAdjust™ technology (the Omnipod 5 interoperable automated glycemic controller, or iAGC) is a software-only medical device intended for the management of type 1 diabetes mellitus. The Omnipod 5 iAGC uses data from a connected iCGM along with user-defined parameters to predict future glucose trends and automatically increase, decrease, or pause the delivery of insulin via a compatible alternate controller enabled (ACE) pump.
The SmartAdjust™ technology software is part of the Omnipod 5 Automated Insulin Delivery System, which also includes the Omnipod 5 ACE Pump (K203768), Omnipod 5 Bolus Calculator (K203772), and an integrated continuous glucose monitor (iCGM, Dexcom G6, most recently cleared under K201328). The SmartAdjust™ technology is intended to be digitally connected to an iCGM and an ACE Pump.

The SmartAdjust™ technology software resides on the Omnipod 5 ACE Pump (the Omnipod 5 Pod and Omnipod 5 App). The iAGC software is responsible for controlling insulin delivery via compatible ACE Pump when the system is in Automated Mode. iCGM data is transmitted from the iCGM to the ACE Pump via Bluetooth Low Energy technology. The SmartAdjust™ Technology uses this transmitted iCGM data in its calculations. The SmartAdjust™ technology can be turned off, and the Omnipod 5 ACE Pump will operate in Manual Mode, which delivers insulin based on healthcare provider (HCP) or user-defined basal programs.

The SmartAdjust™ technology has three states of operation: Automated Mode, Automated: Limited, and Activity. In Automated Mode, the system calculates insulin delivery every 5 minutes based on the user-customizable glucose target (110–150 mg/dL). Automated: Limited is enabled when the SmartAdjust™ technology is not receiving data from a connected iCGM for 20 minutes or more and during sensor warm-up. While in Automated: Limited, the user will receive no more than pre-programmed basal insulin. When a valid glucose value is received from the iCGM, the SmartAdjust™ technology will resume delivery of insulin in full Automated Mode. Activity is a temporary mode which the user may select for various time durations during automated mode up to 24 hours. With Activity, the algorithm reduces insulin delivery and sets a temporary glucose target to 150 mg/dL. Activity is intended for use during periods when insulin sensitivity is expected to be higher, such as during exercise.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

SmartAdjust™ technology

B Predicate 510(k) Number(s):

K220394

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232741	K220394
Device Trade Name	SmartAdjust™ technology	SmartAdjust™ technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. SmartAdjust™ technology is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older. SmartAdjust™ technology is intended for single patient use and requires a prescription.	Same
General Device Characteristic Differences		
iCGM Performance Specifications per 21 CFR 862.1356(1)(iv)	iCGM performance specifications defined for the sensor lifetime performance and includes specifications. for iCGMs with labeled adjunctive use for periods of up to 12 hours.	iCGM performance specifications defined for the sensor lifetime performance.

V Standards/Guidance Documents Referenced:

- ANSI AAMI ISO 14971:2019 – Medical devices – Applications of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016 – Medical device software – Software life cycle processes

VI Performance Characteristics:

A Analytical Performance:

The SmartAdjust™ technology is a software-only device, therefore analytical performance characteristics are not applicable.

B Other Supportive Instrument Performance Characteristics Data:

The updated SmartAdjust™ performance specifications for compatible iCGMs were validated via dynamic in-silico simulations designed to evaluate the glucose control performance of SmartAdjust™ technology in an iCGM error model structure. The in-silico population was distributed by age and total daily insulin requirements that was statistically representative of the intended use population, and included virtual subjects derived as digital twins from subjects in the pivotal clinical study (K203774). Each virtual subject was challenged with 6480 simulation scenarios with varying combinations of virtual glycemic conditions (e.g., iAGC glucose target, starting glucose level, meal profiles, and variation in insulin needs) and iCGM error (e.g., sensing lag, sensor bias, and measurement noise) over a duration of 12 hours to simulate pre-prandial conditions, post prandial glucose excursions and insulin responses of the SmartAdjust™ technology. All simulation results were analyzed for the potential risk of hypoglycemia, potential risk of hyperglycemia, and the glycemic outcomes (time in range, time above range, time below range) when comparing simulated outcomes before and after the change to compatible iCGM performance specifications. The results of the simulations were reviewed and found to be adequate to support the iCGM performance specifications required for the connected continuous glucose monitor in accordance with 21 CFR 862.1356(b)(1)(iv).

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.