510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K220394

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

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:

Not applicable.

III 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.

At the time of device authorization, the compatible integrated continuous glucose monitor (iCGM) is the Dexcom G6 iCGM.

IV Device/System Characteristics:

A 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.

B Instrument Description Information:

1. Instrument Name:

   SmartAdjust™ technology

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):
SmartAdjust technology

B Predicate 510(k) Number(s):
K203774

C Comparison with Predicate(s):

Device & Predicate Device(s):	K220394	K203774
Device Trade Name	SmartAdjust™ technology	SmartAdjust technology
General Device Characteristic Similarities		
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. SmartAdjust™ technology is intended for single patient use and requires a prescription.	Same

Device & Predicate Device(s):	K220394	K203774
General Device Characteristic Differences		
User Age	Ages 2 and older	Ages 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 SmartAdjust™ technology 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:

Omnipod 5 Automated Insulin Delivery System Pivotal Study: Preschool Cohort

This study evaluated the safety and effectiveness of the Omnipod 5 System, including the SmartAdjust™ technology and SmartBolus Calculator, while in Automated Mode (closed-loop). This was a single-arm, multi-center, prospective clinical study that enrolled 80 subjects aged 2.0-5.9 years with type 1 diabetes across 10 clinical sites.

The study was conducted in three outpatient phases. Phase 1 consisted of a 14-day standard therapy phase followed by Phase 2 which consisted of a 13-week hybrid closed-loop phase. Phase 3 is the extension phase and is currently ongoing.

Study Feature	**Description**
Title	Evaluating the safety and effectiveness of the Omnipod Horizon™ (Omnipod 5) Automated Glucose Control System in children with type 1 diabetes aged 2.0-5.9 years: preschool cohort
Study Design	Single-arm, multi-center, prospective clinical study
Number of Sites	Ten (10) US clinical sites
Population	80 subjects aged 2.0-5.9 years with type 1 diabetes Key Inclusion Criteria • Age 2-5.9 years old • Diagnosed with type 1 diabetes • A1C < 10% at screening visit Key Exclusion Criteria • Use of non-insulin anti-diabetic medication other than metformin
Sample Size	80 subjects were enrolled and completed the study
Protocol Overview/Synopsis	The study consisted of three outpatient phases: • Phase 1: 14-day standard therapy (ST) phase • Phase 2: 13-week hybrid closed-loop (HCL) phase • Phase 3 is currently ongoing and consists of a hybrid closed-loop extension and was not reported in this submission.

	Current and non-Dexcom G6 iCGM users who did not meet the minimum CGM data requirements participated in Phase 1 (where subjects managed their diabetes at home per their usual routine and remained on their current MDI or pump therapy, and sensor, if applicable). After completion of the standard therapy phase, subjects were trained on the system and transitioned to Phase 2 initiating treatment with the Omnipod 5 System. A subset of subjects participated in prescribed challenges during any consecutive 2-day period during Phase 2. Subjects who completed Phase 2 could commence their participation in Phase 3.

Participant baseline characteristics including demographics at enrollment:

Characteristic	**Enrolled**
Age (years) ± SD	4.7 ± 1.0
Height (cm) ± SD	108.4 ± 8.7
Weight (kg) ± SD	19.7 ± 3.3
BMI (kg/m^2) ± SD	16.7 ± 1.5
A1C* (%) ± SD	7.4 ± 1.0
Duration of diabetes (years) ± SD	2.3 ± 1.1
Previous or current pump use	68/80 (85.0%)
Previous sensor use	78/80 (97.5%)
Gender	
Female	46/80 (57.5%)
Male	34/80 (42.5%)
Race (not mutually exclusive)	
American Indian or Alaska Native	0/80 (0.0%)
Asian	5/80 (6.3%)
Black or African American	7/80 (8.8%)
Native Hawaiian or Other Pacific Islander	0/80 (0.0%)
White	72/80 (90.0%)
Other	1/80 (1.3%)
Ethnicity	
Hispanic or Latino	7/80 (8.8%)
Not Hispanic or Latino	73/80 (91.3%)

± values are average ± standard deviation (SD); results reported with number in parentheses afterwards represents number of subjects (% of subjects)
**: Point of care A1C used to determine subjects' eligibility for the study.*

Pivotal Study Safety Results:
In the 80 subjects enrolled in the preschool cohort of 2.0-5.9 years, there were zero (0) deaths reported. There were zero (0) serious adverse events and zero (0) unanticipated adverse device effects (UADE) reported during Phase 2 of the study. A total of 29 non-serious adverse events were reported in Phase 2 of HCL in 21 participants, with 20 events classified as prolonged hyperglycemia, 4 events classified as hyperglycemia, and 5 events classified as other.

Pivotal Study Observed Results:
The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month OmniPod 5 System treatment phase. The

primary results of the study included change in time in range (70-180 mg/dL) and average HbA1c%.

CGM Results Overall

Characteristic	Standard Therapy	OmniPod 5	Change*
Average % time 70-180 mg/dL (SD)	57.2 (15.3)	68.1 (9.0)	10.9 (9.6)
Average sensor glucose, mg/dL (SD)	171.1 (30.5)	157.4 (16.8)	-13.7 (19.9)
Average standard deviation of sensor glucose, mg/dL (SD)	64.9 (13.4)	59.6 (10.3)	-5.3 (8.0)
Average coefficient of variation of sensor glucose, % (SD)	38.1 (5.5)	37.7 (4.0)	-0.4 (4.2)
Median % time <54 mg/dL (Q1, Q3)	0.24 (0.05, 0.84)	0.26 (0.16, 0.60)	0.06 (-0.30, 0.16)
Median % time <70 mg/dL (Q1, Q3)	2.19 (0.89, 4.68)	1.94 (1.18, 3.43)	-0.27 (-1.54, 0.46)
Average % time >180 mg/dL (SD)	39.4 (16.7)	29.5 (9.8)	-9.9 (10.5)
Average % time ≥250 mg/dL (SD)	14.8 (12.1)	9.2 (5.6)	-5.6 (8.9)
Average % time ≥300 mg/dL (SD)	6.0 (7.3)	3.2 (2.8)	-2.7 (6.1)

**Change is calculated as per-subject time in range during HCL phase minus per-subject time in range during ST.*
SD=standard deviation, Q1=interquartile range 1, Q3=interquartile range 3

CGM Results Overnight (12:00 AM to 6:00 AM)

Characteristic	Standard Therapy	OmniPod 5	Change
Average % time 70-180 mg/dL (SD)	58.2 (18.7)	81.0 (10.0)	22.8 (14.8)
Average sensor glucose, mg/dL (SD)	168.1 (33.3)	140.7 (16.4)	-27.4 (25.4)
Average standard deviation of sensor glucose, mg/dL (SD)	58.0 (14.0)	45.5 (10.8)	-12.5 (11.5)
Average coefficient of variation of sensor glucose, % (SD)	34.7 (6.6)	32.1 (5.2)	-2.6 (6.7)
Median % time <54 mg/dL (Q1, Q3)	0.00 (0.00, 0.97)	0.18 (0.06, 0.53)	0.00 (-0.51, 0.13)
Median % time <70 mg/dL (Q1, Q3)	1.66 (0.40, 4.21)	1.58 (0.65, 2.89)	-0.44 (-2.17, 0.63)
Average % time >180 mg/dL (SD)	38.4 (20.1)	16.9 (10.3)	-21.5 (16.0)
Average % time ≥250 mg/dL (SD)	13.1 (13.2)	3.9 (3.9)	-9.1 (11.4)
Average % time ≥300 mg/dL (SD)	4.3 (6.7)	1.2 (1.6)	-3.1 (6.1)

CGM Results at Various Target Glucose Settings

Characteristic	110 mg/dL Target Glucose (n=47)	120 mg/dL Target Glucose (n=61)	130 mg/dL Target Glucose (n=47)	140 mg/dL Target Glucose (n=20)	150 mg/dL Target Glucose* (n=16)
Average % time 70-180 mg/dL (SD)	69.3 (9.5)	68.3 (11.3)	67.3 (14.6)	63.0 (11.9)	65.0 (15.0)
Average sensor glucose, mg/dL (SD)	152.8 (17.6)	156.5 (20.6)	161.3 (25.2)	169.2 (18.1)	169.3 (20.3)
Median % time <54 mg/dL (Q1, Q3)	0.33 (0.16, 0.73)	0.22 (0.14, 0.53)	0.17 (0.05, 0.68)	0.17 (0.03, 0.53)	0.06 (0.00, 0.21)
Median % time <70 mg/dL (Q1, Q3)	2.39 (1.48, 3.91)	1.63 (1.11, 2.73)	1.41 (0.60, 2.86)	1.43 (0.37, 2.66)	0.79 (0.13, 1.95)
Average % time >180 mg/dL (SD)	27.6 (10.5)	29.3 (12.1)	30.4 (15.4)	35.4 (12.2)	33.9 (15.0)
Average % time ≥250 mg/dL (SD)	7.7 (5.9)	8.9 (6.2)	10.6 (9.4)	12.6 (6.2)	11.4 (7.2)
Cumulative number of person-days	2438.4	3083.5	1066.6	404.0	237.0

**Glycemic measures reported at the 150 mg/dL Target Glucose setting only included those with Activity mode turned OFF.*

Change in Insulin Requirements During the Study

Characteristic	Standard Therapy	OmniPod 5	Change*
Average total daily insulin, U/kg (SD)	0.69 (0.18)	0.71 (0.15)	0.02 (0.10)
Average total daily basal insulin, U/kg (SD)	0.28 (0.12)	0.32 (0.10)	0.04 (0.11)
Average total daily bolus insulin, U/kg (SD)	0.41 (0.15)	0.39 (0.10)	-0.02 (0.10)

**Change is calculated as insulin requirements during OmniPod 5 phase minus insulin requirements during standard therapy phase.*

Body Mass Index Results

The table below provides information on the average body mass index (BMI), which is a measure of weight adjusted for height; and BMI z-score, which is a measure of weight adjusted for height, sex, and age, during the standard therapy phase and the 3-month OmniPod 5 System treatment phase (Phase 2).

Characteristic	Standard Therapy	OmniPod 5	Change
Average BMI, kg/m^3 (SD)	16.7 (1.5)	16.7 (1.4)	0.1 (1.0)
Average BMI z-score (SD)	0.74 (0.95)	0.76 (0.89)	0.05 (0.63)

Change in HbA1c from the Study

The table below provides information on the average change in HbA1c% from the beginning of the study (baseline) to the end of the 3-month Omnipod 5 System treatment phase. Participants

experienced a reduction in HbA1c after 3 months of Omnipod 5 System use regardless of baseline HbA1c < 8% or ≥ 8% category.

	Baseline HbA1c <8% (n=55)			Baseline HbA1c ≥8% (n=25)		
Characteristic	**Baseline**	**OmniPod 5**	**Change**	**Baseline**	**OmniPod 5**	**Change**
Average HbA1c% (SD)	6.9 (0.6)	6.6 (0.6)	-0.31 (0.39)	8.5 (0.5)	7.5 (0.4)	-1.06 (0.60)

Subgroup Analysis of Average Results by Baseline Treatment
The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use.

	MDI (n=12)		Insulin Pump (n=68)	
Characteristic	**Standard Therapy**	**OmniPod 5**	**Standard Therapy**	**OmniPod 5**
Average % Time in range 70-180 mg/dL	48.4	61.8	58.7	69.2
Median % time <70 mg/dL	1.45	1.48	2.44	2.00
Average HbA1c%	8.4	7.5	7.3	6.8

2. Human Factors Testing:

Human factors validation testing was conducted with the Omnipod 5 App installed on a compatible mobile device with interoperable technology. The final device design was evaluated in the summative study performed with 16 representative participants (i.e., caregivers of children 2-5.9 years old) interacting with the device in a simulated use environment. All study participants received training that was consistent with the training that patients would receive with the commercial product. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the device could be used safely by intended users in the intended use environment when used in combination with a digitally connected device.

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.