510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K203774

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:
New device

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 6 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 in anyone under the age of 6 years old. SmartAdjust technology should also NOT be used in people who require less than 6 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 Tomography (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). 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, by setting a temporary glucose target to 150mg/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):
Control-IQ Technology

B Predicate 510(k) Number(s):
K200467

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203774	K200467
Device Trade Name	SmartAdjust Technology	Control-IQ Technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	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. (It) is intended for the management of	Same

	type 1 diabetes mellitus in persons 6 years of age and older.	
Age Range of intended users	Ages 6 years and older	Same
Communication and Pairing	Bluetooth Low Energy (BLE)	Same
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 insulins: NovoLog, Humalog, and Admelog	U-100 Insulins: NovoLog and Humalog
Device Hosting Controller	OP5 Pod (ACE Pump) and Android OS device (locked down PDM or user's compatible smart phone)	T:slim X2 insulin pump
Alarms/Alerts	• Out of Range Alert • Low Alert • Maximum Insulin/Delivery Alert	• Out of Range Alert • Low Alert • High Alert • Maximum Insulin/Delivery Alert
Target Glucose Range	110-150 mg/dL	112.50-160 mg/dL

VI Standards/Guidance Documents Referenced:

Special controls established under 21 CFR 862.1356.

ISO 14971:2007: Medical Devices - Application of Risk Management to Medical Devices FDA Recognition No: 5-40

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

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:

For the evaluation of the system in the clinical studies, the SmartAdjust technology was installed on the Omnipod 5 ACE Pump (Pod) insulin pump with interoperable technology (K203768), which was paired with the Dexcom G6 integrated continuous glucose monitor (iCGM). Details on the performance characteristics of these devices can be found in the public decision summaries for each device.

Summary of Clinical Testing:

Two clinical studies were conducted to evaluate the SmartAdjust technology in subjects 6-70 years of age with type 1 diabetes. The first study was the pre-pivotal study which was followed by the pivotal study.

Pre-pivotal

Study Feature	**Description**
Title	Pre-pivotal evaluation of the safety and effectiveness of the Omnipod Horizon Automated Glucose Control System in patients with type 1 diabetes
Study Design	Single-arm, multi-center, prospective clinical study
Number of Sites	Six (6) US clinical sites
Population	18 subjects aged 6-13.9 years, and 18 subjects aged 14-70 years. Key Inclusion Criteria • Age 6-70 years old • Type 1 diabetes for at least 6 months • Hemoglobin A1c (HbA1c) <10% at screening Key Exclusion Criteria • Use of non-insulin anti-diabetic medication other than metformin
Protocol Overview/Synopsis	The study consisted of two phases: 1. 14 day outpatient standard therapy phase followed by; 2. 14 day hybrid closed-loop phase

Study Feature	Description
	For the standard therapy (ST) phase, current Dexcom G6 iCGM users could provide data from a 14-day period within the last 30 days. For non-G6 users, subjects wore a study iCGM, in blinded mode, to record glucose measurements over 14 days while subjects managed their diabetes at home per their usual routine and remained on their current multiple daily injection (MDI) or pump therapy, and sensor, if applicable. After completion of the standard therapy phase, subjects were trained on the system and transitioned to the hybrid closed-loop (HCL) phase initiating treatment with the Omnipod Horizon™ System. For the hybrid closed-loop phase, subjects were divided into two groups: Group 1: N=16 subjects aged 6.0-70.0 years participated in the hybrid closed-loop phase for the first 2-days while in a supervised hotel/rental house environment and then transitioned to a 12 day outpatient environment. • N=8 subjects aged 6.0-13.9 years • N=8 subjects aged 14.0-70.0 years Group 2: N=20 subjects aged 6.0-70.0 years participated in the hybrid closed-loop phase in a 14 day outpatient environment with • N=10 subjects aged 6.0-13.9 years • N=10 subjects aged 14.0-70.0 years After all subjects from the first group completed the 2 day hotel phase, the second group of subjects could commence hybrid closed-loop. All subjects participated in target glucose challenges during the hybrid closed-loop phase. In total, all subjects completed 14 days of hybrid closed-loop, with approximately 72 hours spent at each target blood glucose challenge level of 130 mg/dL, 140 mg/dL and 150 mg/dL. Clinical site staff received alerts through a remote monitoring system during the study for real-time assessments of subject safety. After each subject in the pre-pivotal study successfully completed 14 days of hybrid-closed loop, they could immediately enroll into the pivotal study.

Pre-Pivotal Study Safety Results:

There were no serious device-related adverse events reported during the pre-pivotal study. Additionally, there were no subjects with severe hypoglycemia (SH) or diabetic ketoacidosis (DKA) reported during the HCL phase of the pre-pivotal study.

Pre-Pivotal Study Observed Results:

CGM Data at Various Target Glucose Settings

Overall (24 hours) CGM results at target glucose settings in children (6 to 13.9 years) from Pre-pivotal study

Characteristic	**110mg/dL Target Glucose (n=11)**	**120mg/dL Target Glucose (n=3)**	**130mg/dL Target Glucose (n=18)**	**140mg/dL Target Glucose (n=18)**	**150mg/dL Target Glucose (n=18)**
Avg % time 70-180 mg/dL (std dev)	**71.2% (10.2%)**	**66.8% (12.9%)**	**61.5% (7.7%)**	**64.8% (11.6%)**	**53.5% (11.0%)**
Avg sensor glucose, mg/dL (std dev)	155.2 (18.2)	170 (16)	174.1 (11.4)	172.7 (17.2)	182.9 (15.3)
% Time in glucose range					
Median % <54 mg/dL (Q1, Q3)	0.1% (0.0, 0.4)	0.2% (0.0, 0.3)	0.0% (0.0, 0.3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.1)
Median % <70 mg/dL (Q1, Q3)	0.9% (0.4, 2.8)	0.3% (0.2. 2.2)	0.5% (0.1, 0.8)	0.1% (0.0, 0.5)	0.5% (0.0, 0.8)
Avg % >180 mg/dL (std dev)	27.1% (11.4%)	32.3% (11.9%)	37.7% (7.9)	34.6% (12.1%)	45.9% (11.0%)
Avg % ≥250 mg/dL (std dev)	6.8% (6.3%)	14.4% (6.2%)	13.2% (5.8%)	10.6% (7.3%)	12.8% (8.1%)
Cumulative number of person-days	47.7	8.7	73.3	56.3	61.5

Overall (24 hours) CGM results at target glucose settings in adolescents and adults (14 to 70 years) from Pre-pivotal study

Characteristic	**110mg/dL Target Glucose (n=12)**	**120mg/dL Target Glucose (n=7)**	**130mg/dL Target Glucose (n=18)**	**140mg/dL Target Glucose (n=18)**	**150mg/dL Target Glucose (n=18)**
Avg % time 70-180 mg/dL (std dev)	**72.5% (9.4%)**	**70.9% (11.3%)**	**75.1% (11.6%)**	**67.6% (9.2%)**	**63.7% (7.8%)**
Avg sensor glucose, mg/dL (std dev)	153.8 (14.8)	159.7 (11)	153.8 (14.9)	165.4 (11.5)	169.8 (9.4)
% Time in glucose range					
Median % <54 mg/dL (Q1, Q3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.0)	0.0% (0.0, 0.2)	0.0% (0.0, 0.1)	0.0% (0.0, 0.2)
Median % <70 mg/dL (Q1, Q3)	0.5% (0.0, 1.4)	0.4% (0.0, 0.6)	0.9% (0.4, 1.2)	0.1% (0.0, 0.6)	0.2% (0.0, 0.9)
Avg % >180 mg/dL (std dev)	26.4% (10.0%)	28.7% (11.2%)	23.4% (11.4%)	31.7% (9.2%)	35.7% (7.9%)
Avg % ≥250 mg/dL (std dev)	4.1% (3.4%)	5.2% (5.5%)	5.0% (4.6%)	5.1% (4.5%)	6.0% (4.8%)
Cumulative number of person-days	41.1	28	58.8	58.4	60.3

Pivotal Study

The Pivotal study evaluated the safety and effectiveness of the SmartAdjust technology in patients with type 1 diabetes. The study was a single-arm, multi-center, prospective clinical study that enrolled 240 subjects 6-70 years of age, across 17 clinical sites to obtain at least 100 evaluable subjects in the 6.0-13.9 years of age cohort and at least 100 evaluable subjects in the 14.0-70.0 years of age cohort.

The Pivotal 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 Automated Glucose Control System in patients with type 1 diabetes
Study Design	Single-arm, multi-center, prospective clinical study
Number of Sites	Seventeen (17) US clinical sites
Population	112 subjects aged 6-13.9 years, and 129 subjects aged 14-70 years. Key Inclusion Criteria • Age 6-70 years old • Type 1 for at least 6 months • HbA1c <10% at screening Key Exclusion Criteria • Use of non-insulin anti-diabetic medication other than metformin
Sample Size	240 subjects were enrolled and completed the study
Protocol Overview/Synopsis	The study consisted of three phases: 3. 14 day outpatient therapy phase (Phase 1) 4. 13 week outpatient hybrid closed-loop phase (Phase 2) 5. Hybrid closed-loop extension phase (Phase 3) 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 Horizon System. Subjects in each cohort (ages 6-13.9 and 14-70 years) participated in prescribed challenges during any consecutive 5-day period during Phase 2 of the hybrid closed-loop phase. Subjects who completed Phase 2 could commence their participation in Phase 3.

Baseline characteristics including demographics at enrollment (N=240)

Characteristic	Children (6 to 13.9 years)	Adults (14 to 70 years)
n	112	128
Age (years) ± SD	10.3 ± 2.2	36.9 ± 13.9
Duration of diabetes (years)	4.7 ± 2.6	17.9 ± 11.6
HbA1c[§]	7.67% ± 0.95%	7.16% ± 0.86%
Daily insulin dose (U/kg) [¥]	0.85 ± 0.24	0.61 ± 0.22
Body mass index (BMI)	18.6 ± 3.2	26.6 ± 4.7
Female sex	60 (53.6%)	78 (60.9%)
Previous [¶] or current continuous glucose monitor (CGM) use	108 (96.4%)	126 (98.4%)
Previous[¶] or current pump use	100 (89.3%)	115 (89.8%)
Race / Ethnicity[‡]		
White	110 (98.2%)	118 (92.2%)
Hispanic or Latino	8 (7.1%)	10 (7.8%)
Black or African American	5 (4.5%)	5 (3.9%)
Asian	3 (2.7%)	2 (1.6%)
Native Hawaiian or other Pacific Islander	1 (0.9%)	0 (0.0%)
American Indian or Alaska Native	0 (0.0%)	4 (3.1%)

Plus-minus values are average ± standard deviation; results reported with number in brackets afterwards represent number of subjects (% of subjects)

[§] *Glycated hemoglobin determined from laboratory assessment*

[¥] *Baseline total daily insulin dose was determined from data collected during the standard therapy phase*

[¶] *Previous use is defined as having used the device for any duration in the past*

[‡] *Race and ethnicity were reported by the subjects. Groups are not mutually exclusive*

Pivotal Study Safety Results

One (1) DKA, and 3 SH events were reported during the study and included:

- One (1) DKA and 1 SH occurred in the aged 6.0-13.9 years cohort
- Two (2) SH occurred in the 14.0-70.0 years cohort.

The DKA event was indicated as possibly related to the study device and not related to the study procedures while all other serious adverse events were indicated as not related to the device and not related to the study procedures.

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. There were 3 severe hypoglycemia events not attributable to the Omnipod 5 System automated insulin delivery or system malfunction and 1 DKA event from a suspected infusion site failure. Other related, but non-glycemic adverse events included infection or irritation at infusion site (2 children, 2 adults).

Adverse events during the Omnipod 5 System phase

Adverse Event Type	**Children (6 to 13.9 years) (n=112)**	**Adults (14 to 70 years) (n=128)**	**Total (6 to 70 years) (N=240)**
Primary Safety Endpoints			
Hypoglycemia ‡	1	0	1
Severe Hypoglycemia §	1	2	3
DKA	1	0	1
Hyperglycemia ‖	1	2	3
Prolonged Hyperglycemia **	13	5	18
Other	8	8	16

‡ *Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia*

§ *Required the assistance of another person*

‖ *Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event*

** *Meter blood glucose measuring ≥300mg/dL and ketones >1.0mmol/L*

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 average HbA1c% and % time in range (70-80mg/dL).

CGM results overall (24 hours)

Characteristic	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg HbA1c% (std dev)	7.67% (0.95%)	6.99% (0.63%)	-0.71%	7.16% (0.86%)	6.78% (0.68%)	-0.38%
Avg % time 70-180mg/dL (std dev)	52.5% (15.6%)	68.0% (8.1%)	15.6%	64.7% (16.6%)	73.9% (11.0%)	9.3%
Avg sensor glucose, mg/ dL (std dev)	183 (32)	160 (15)	-23	161 (28)	154 (17)	-8
Avg standard deviation of sensor glucose, mg/dL (std dev)	68 (13)	60 (10)	-9	57 (14)	49 (11)	-8
Avg coefficient of variation of sensor glucose, % (std dev)	37.5% (5.1%)	37.0% (3.9%)	-0.4%	35.2% (5.7%)	31.7% (4.7%)	-3.5%
% Time in Glucose Range						
Median % <54mg/dL (Q1, Q3)	0.10% (0.00, 0.41)	0.23% (0.08, 0.42)	0.04%	0.22% (0.00, 0.77)	0.17% (0.06, 0.28)	-0.08%
Median % <70mg/dL (Q1, Q3)	1.38% (0.42, 2.67)	1.48% (0.65, 2.23)	0.06%	2.00% (0.63, 4.06)	1.09% (0.46, 1.75)	-0.89%
Avg % >180mg/dL (std dev)	45.3% (16.7%)	30.2% (8.7%)	-15.1%	32.4% (17.3%)	24.7% (11.2%)	-7.7%
Avg % ≥250mg/dL (std dev)	19.1% (13.1%)	9.6% (5.4%)	-9.4%	10.1% (10.5%)	5.8% (5.5%)	-4.3%
Avg % ≥300mg/dL (std dev)	8.5% (8.9%)	3.5% (2.9%)	-5.1%	3.7% (5.5%)	1.7% (2.5%)	-2.0%

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range < 70mg/dL and < 54mg/dL is reported as medians with interquartile ranges in brackets(Q1,Q3). The median is the middle umber in an ascending list of numbers and the interquartile range represents the middle 50% of values.

CGM results overnight (12:00AM to 6:00AM)

	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	**Omnipod 5**	**Change**	**Standard Therapy**	**Omnipod 5**	**Change**
Avg % time 70- 180mg/dL (std dev)	55.3% (19.0%)	78.1% (10.8%)	22.9%	64.3% (19.5%)	78.1% (13.9%)	13.8%
Avg sensor glucose, mg/dL (std dev)	177 (35)	149 (17)	-29	160 (34)	149 (21)	-11
Avg standard deviation of sensor glucose, mg/dL (std dev)	61 (15)	48 (12)	-13	56 (17)	44 (13)	-12
Avg coefficient of variation of sensor glucose, % (std dev)	34.6% (7.1%)	31.9% (5.6%)	-2.8%	35.0% (7.9%)	28.9% (5.8%)	-6.2%
Percentage time in glucose range, %						
Median % <54mg/dL (Q1,Q3)	0.00% (0.00, 0.30)	0.09% (0.02, 0.32)	0.02%	0.00% (0.00, 1.06)	0.09% (0.02, 0.30)	0.00%
Median % <70mg/dL (Q1,Q3)	0.78% (0.00, 2.84)	0.78% (0.37, 1.49)	0.01%	2.07% (0.50, 5.54)	0.82% (0.31, 1.62)	-0.86%
Avg % >180mg/ dL (std dev)	42.2% (20.0%)	20.7% (10.8%)	-21.5%	32.1% (20.2%)	20.7% (14.1%)	-11.3%
Avg % ≥250mg/ dL (std dev)	16.3% (15.0%)	5.4% (5.1%)	-10.9%	10.6% (12.7%)	4.8% (7.0%)	-5.7%
Avg % ≥300mg/ dL (std dev)	6.7% (9.1%)	1.8 (2.5%)	-4.8%	4.2% (8.0%)	1.5% (3.1%)	-2.7%

CGM results at various target glucose settings in Pivotal study
The tables below provide information on the results at various self-selected Target Glucose settings during the 3-month Omnipod 5 System phase of the pivotal study. Of the customizable BG targets, the most selected was 110 mg/dL.

Overall (24 hours) CGM Results at Target Glucose Settings in Children (6 to 13.9 years) from Pivotal Study

Characteristic	**110mg/dL Target Glucose (n=98)**	**120mg/dL Target Glucose (n=74)**	**130mg/dL Target Glucose (n=47)**	**140mg/dL Target Glucose (n=12)**	**150mg/dL Target Glucose* (n=9)**
Avg % time 70-180 mg/dL (std dev)	68.4% (9.1%)	67.5% (9.7%)	64.2% (14.3%)	59.2% (16.9%)	53.3% (18.2%)
Avg sensor glucose, mg/dL (std dev)	159 (17)	163 (16)	169 (24)	178 (24)	183.6 (23.9)
% Time in glucose range					
Median % <54 mg/ dL (Q1, Q3)	0.22% (0.06, 0.49)	0.18% (0.05, 0.33)	0.09% (0.00, 0.21)	0.04% (0.00, 0.34)	0.00% (0.00, 0.00)
Median % <70 mg/ dL (Q1, Q3)	1.51% (0.76, 2.38)	1.16% (0.58, 1.94)	0.71% (0.26, 1.63)	0.59% (0.05, 1.52)	0.12% (0.00, 0.21)
Avg % >180 mg/dL (std dev)	29.7% (9.6%)	31.1% (10.0%)	34.5% (14.8%)	39.9% (16.6%)	46.4% (18%)
Avg % ≥250 mg/dL (std dev)	9.7% (5.8%)	10.0% (6.3%)	11.8% (9.0%)	14.6% (11.1%)	13.3% (11.9%)
Cumulative number of person-days	6,289	2,716	941	99	73

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

Overall (24 hours) CGM results at various target glucose settings in adolescents and adults (14 to 70 years) from Pivotal study

Characteristic	110 mg/dL Target Glucose (n=121)	120 mg/dL Target Glucose (n=54)	130 mg/dL Target Glucose* (n=9)
Avg % time 70-180 mg/dL (std dev)	75.6% (9.9%)	73.4% (12.1%)	63.6% (25.9%)
Avg sensor glucose, mg/dL (std dev)	151 (15)	156 (18)	172 (33)
% Time in glucose range			
Median % <54 mg/dL (Q1, Q3)	0.16% (0.05, 0.26)	0.11% (0.00, 0.33)	0.00% (0.00, 0.00)
Median % <70 mg/dL (Q1, Q3)	0.99% (0.47, 1.67)	0.91% (0.31, 1.68)	0.26% (0.05, 0.63)
Avg % >180 mg/dL (std dev)	23.1% (10.2%)	25.4 % (12.3%)	35.9% (26.1%)
Avg % ≥250 mg/dL (std dev)	5.1% (4.6%)	5.8% (6.4%)	9.6% (12.3%)
Cumulative number of person-days	9,278	1,827	178

**Results for the 140 mg/dL and 150 mg/dL (with Activity mode OFF) Target Glucose settings in adults are not shown due to too few subjects selecting them (n≤2).*

Change in insulin requirements during the Pivotal study

	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	**Omnipod 5**	**Change**	**Standard Therapy**	**Omnipod 5**	**Change**
Avg total daily insulin, U/kg (std dev)	0.85 (0.24)	0.92 (0.25)	0.07	0.61 (0.22)	0.59 (0.21)	-0.02
Avg total daily basal insulin, U/kg (std dev)	0.36 (0.13)	0.47 (0.15)	0.10	0.31 (0.11)	0.30 (0.11)	-0.01
Avg total daily bolus insulin, U/kg (std dev)	0.48 (0.18)	0.45 (0.13)	-0.03	0.31 (0.16)	0.29 (0.12)	-0.01

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 treatment phase in children.

Characteristic	Children (6 to 13.9 years) n=112		
	Standard Therapy	**SmartAdjust Technology**	**Change**
BMI, kg/m^2 (std dev)	18.6 (3.2)	19.2 (3.6)	0.54
BMI z-score (std dev)	0.4 (0.8)	0.4 (0.8)	0.03

Change in HbA1c from the Pivotal study

The table below provides information on the average change in HbA1c% from baseline to the end of the 3-month Omnipod 5 System treatment phase analyzed by baseline HbA1c% in children (6 to 13.9 years) and adolescents and adults (14 to 70 years). Adolescents, adults, and children experienced a reduction in HbA1c after 3 months of Omnipod 5 System use regardless of baseline HbA1c < 8% or ≥ 8% category.

Subgroup analysis of change in average HbA1c(%) by baseline HbA1c(%)

Adolescents & Adults	**Baseline HbA1c <8% (n=105)**			**Baseline HbA1c ≥8% (n=23)**		
	Baseline	**Omnipod 5**	**Change**	**Baseline**	**Omnipod 5**	**Change**
HbA1c% (std dev)‡	6.86% (0.59%)	6.60% (0.53%)	-0.27%	8.55% (0.42%)	7.63% (0.67%)	-0.91%
Children	**Baseline HbA1c <8% (n=73)**			**Baseline HbA1c ≥8% (n=39)**		
	Baseline	**Omnipod 5**	**Change**	**Baseline**	**Omnipod 5**	**Change**
HbA1c% (std dev)	7.11% (0.50%)	6.69% (0.44%)	-0.45%	8.73% (0.63%)	7.56% 0.54%)	-1.18%

‡Average HbA1c values are reported with standard deviation values in brackets.

Study 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.

Subgroup analysis of average results by baseline treatment in children (6 to 13.9 years)

Characteristic	**MDI (n=13)**		**Insulin Pump (n=99)**	
	Standard Therapy	**Omnipod 5**	**Standard Therapy**	**Omnipod 5**
% Time in range 70- 180mg/dL	52%	69%	53%	68%
% Time <70mg/dL‡	1.54%	1.41%	1.38%	1.49%
HbA1c%	7.7%	6.7%	7.7%	7.0%

‡ Values presented for % Time <70mg/dL are medians, the remaining values in the table are averages.

Subgroup analysis of average results by baseline treatment in adolescents and adults (14 to 70 years)

Characteristic	MDI (n=20)		Insulin Pump (n=105)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70- 180mg/dL	60%	72%	66%	74%
% Time <70mg/dL‡	2.38%	0.79%	1.93%	1.16%
HbA1c%	7.6%	7.0%	7.1%	6.7%

SmartAdjust technology (Auto Mode) use

The table below provides information on the average % of time study subjects used the Omnipod 5 System in Automated Mode.

Percent time spent in Automated Mode

	Children (6 to 13.9 years) n=112	Adults (14 to 70 years) n=128
% Time in Automated Mode (std dev)	95.2% (4.0%)	94.8% (6.0%)

a. *Human Factors Testing*

Human factors validation tests were conducted with the Omnipod 5 App installed on a compatible mobile device with interoperable technology. A total of 7 formative studies were conducted; after each study, information was fed back into the design of the User Interface. The final device design was evaluated in the summative study performed with 64 representative participants 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.

b. Insulin Compatibility:

The SmartAdjust technology used with the Omnipod 5 System is designed to use rapid-acting U-100 insulins including: NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro). These insulins were used in the pivotal clinical study for this device and no other insulins have been tested for use with the device.

c. Data Logging:

Software verification testing has demonstrated the device records timestamped critical events, including information related to its state, user inputs, and device settings, as required by the special controls.

d. Interoperability:
A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, the plans provided by the sponsor covered their approach to working with connected device companies regarding contractual issues, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).
The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

e. Cybersecurity:
Detailed information on cybersecurity of the device was reviewed and found to be acceptable. The sponsor also provided a software bill of materials, which provided details on all software used in the device and the hardware platform that the device was installed on. This included all manufacturer-developed, commercially licensed, open source, and off-the-shelf software components (including firmware as relevant), along with an identification of the hardware runtime environment in which each resides, with relevant version and/or model information, as well as details on whether each component was actively supported by its manufacturer or legacy licensed.

f. Postmarket Surveillance Study
There is uncertainty remaining regarding the risk/benefit profile of the device when used in the broader intended use population. While the premarket clinical study provided to support the 510(k) showed some benefits, it was not adequately powered to assess differences in the rates of safety events (e.g., diabetic ketoacidosis and severe hypoglycemia).
Accordingly, a postmarket surveillance study will be ordered by FDA to confirm understanding of safety.

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.