510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K261461

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod 6 algorithm

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	Class II	21 CFR 862.1356	CH – Clinical Chemistry

E Purpose for Submission:

New device.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Omnipod 6 algorithm 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.

The Omnipod 6 algorithm is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older.

The Omnipod 6 algorithm is intended for single patient use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

- DO NOT use the Omnipod 6 algorithm in pregnant women, critically ill patients, and those on dialysis. The safety of the Omnipod 6 algorithm has not been evaluated in these populations. Consult with your healthcare provider if any of these conditions apply to you before using the Omnipod 6 algorithm.
- The Omnipod 6 algorithm should NOT be used by anyone under the age of 2 years old. The Omnipod 6 algorithm 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 the Omnipod 6 System if you do not have adequate vision and/or hearing to recognize all functions of the Omnipod 6 System including alerts, alarms, and reminders according to instructions.
- Do NOT use Omnipod 6 System with a Dexcom sensor if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom sensor readings could be falsely elevated and could result in over-delivery of insulin which can lead to severe hypoglycemia.
- DO NOT use the Omnipod 6 System with the Libre 2 Plus or Libre 3 Plus sensor if you are taking more than 1000 mg of ascorbic acid (Vitamin C) per day, a substance found in supplements like multivitamins or cold remedies such as Airborne and Emergen-C. Taking more than 1000 mg of Vitamin C per day may falsely raise your sensor readings and result in over-delivery of insulin that could result in severe hypoglycemia.
- DO NOT use the Omnipod 6 System in oxygen rich environments (greater than 25% oxygen), which include home or surgical areas that use supplementary oxygen and hyperbaric chambers. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to oxygen rich environments could result in combustion of the Pod or Omnipod 6 Controller, which can cause severe burns to the body.
- DO NOT use the Omnipod 6 System at low atmospheric pressure (below 700 hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters). Change in atmospheric pressure can also occur during take-off with air travel. Unintended insulin delivery can occur if there is expansion of tiny air bubbles that may exist inside the Pod. This can result in hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.
- DO NOT use the Omnipod 6 System in high atmospheric pressure environments (above 1060 hPA), which can be found in a hyperbaric chamber. Hyperbaric, or high pressure, chambers, are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to high atmospheric pressure environments can damage your Pod and Omnipod 6 Controller which could result in under-delivery of insulin which can lead to hyperglycemia.
- ALWAYS remove and dispose of the Pod before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, place the Controller or smartphone outside of the procedure room. Exposure to X-ray, MRI, or CT

treatment can damage these components. Check with your healthcare provider for Pod removal guidelines.

- DO NOT expose any Omnipod 6 System products or supplies to extreme temperatures as this results in them not functioning properly. Store all Omnipod 6 System products and supplies, including unopened Pods, in a cool, dry place.

III Device Description

The candidate device is the Omnipod 6 algorithm, a software-only component of the Omnipod 6 Automated Insulin Delivery (AID) System that includes the following devices as well:

- Omnipod 6 ACE Pump that is identical to the Omnipod 5 ACE Pump.
- SmartBolus Calculator that is identical to the one used in the Omnipod 5 Automated Insulin Delivery (AID) System.
- Third-party iCGM (cleared for use with Dexcom G6 and G7, and Abbott Freestyle Libre 2)

The Omnipod 6 System is a hybrid closed loop system and can operate in Manual Mode (Omnipod 6 algorithm is not enabled) and Automated Mode (Omnipod 6 algorithm is enabled). Automated Mode operation requires connected iCGM, and the algorithm adjusts insulin delivery through micro-boluses, based on Estimated Glucose Values (EGV) from the iCGM and past insulin delivery history. Automated Mode has three states of operation:

1. Fully Automated: In fully Automated mode, the Algorithm calculates and adjusts insulin delivery based on several factors including the user's set target glucose (100-150 mg/dL), total daily insulin (TDI), and sensor glucose values.
2. Automated: Limited (Limited Mode): Enabled when the iAGC is not receiving data from a connected iCGM for 20 minutes or more or during sensor warm up. While in Limited Mode, the user will receive basal insulin at or below either the pre-programmed basal rate or the rate based on past insulin usage, whichever is less. Once the iAGC and iCGM are back into range and a valid EGV is received from the iCGM, the system will resume delivery of insulin in fully Automated mode.
3. Activity: Intended for use during periods when insulin sensitivity is expected to be higher, such as during exercise. The feature can be set for various time durations during Automated mode. With Activity, the algorithm reduces insulin delivery by setting a temporary glucose target to 150 mg/dL. Activity has a maximum selectable duration of 24 hours.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod 5 algorithm

B Predicate 510(k) Number(s):

K251779

C Comparison with Predicate(s):

Device & Predicate Device(s):	K261461	K251779
Device Trade Name	Omnipod 6 algorithm	Omnipod 5 algorithm
General Device Characteristic Similarities		
Intended Use/Indications For Use	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. Intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. Intended for single patient use and requires a prescription.	Same
Compatible Insulin	NovoLog, Humalog, Admelog, and Kirsty U-100 insulins	Same
Target Glucose Control Range	100-150 mg/dl, user-customizable	Same
General Device Characteristic Differences		
Adaptive rate	Automatically adjusted adaptive rate personalized to to user's insulin history and bolus behavior	Adaptive rate that automatically adjusts to user's insulin history

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
- ISO 14155 Third edition 2020-07, Clinical investigation of medical devices for human subjects – Good clinical practice
- ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices – Information to be supplied by the manufacturer

VI Performance Characteristics:

A. Non-Clinical Performance

Non-clinical performance is leveraged from the predicate submission.

B. Clinical Studies:

Summary of Clinical Testing

A randomized crossover pivotal study was conducted to evaluate safety and efficacy of the Omnipod 6 algorithm by comparing the Omnipod 6 System (formerly called Omnipod 5 SmartAdjust 2.0, or OP5SA2.0, or OP5SA) with the Omnipod 5 System (OP5) in individuals with type 1 or type 2 diabetes. A summary of the pivotal clinical study is provided in the following table:

Study Feature	Description
Title	Safety and Efficacy of the Omnipod 5 SmartAdjust 2.0 System Compared to the Omnipod 5 System in Individuals with Type 1 and Type 2 Diabetes (STRIVE)
Study Design	A multi-center, randomized two-sequence crossover study (Periods 1 and 2) designed to compare the Omnipod 5 SA 2.0 System at a target of 100 mg/dL (OP5SA100 treatment group) to the commercially available Omnipod 5 System at a target of 110 mg/dL (OP5110 treatment group). All participants who completed Periods 1 and 2 continued to the Restricted Bolus phase (Period 3), during which all participants used the Omnipod 5 SA 2.0 System at a target of 100 mg/dL with a goal of no more than 3 insulin boluses per day.
Investigational Device	Omnipod 6 (or OP5SA) System: modified version of OP5 Pod (updated software - Omnipod 6 algorithm Pod), modified version of the US OP5 app on a compatible Smartphone/Controller (Omnipod 6 App), and Dexcom G6 CGM. The OP5 System: OP5 Pod (commercial product), OP5 App (installed on the Insulet-provided commercially equivalent Controller or smartphone), and Dexcom G6 CGM.
Investigational Sites	Eleven (11) sites in the United States enrolled participants.
Study Population	• Type 1 Diabetes: diagnosed with type 1 diabetes for at least 3 months for participants aged 2 to < 7 years and at least 1 year for participants aged 7 to 70 years OR • Type 2 Diabetes: diagnosed with type 2 diabetes for at least 1 year for participants aged 18 to 70 years
Protocol Overview	During Period 1, study participants were randomly assigned to either the OP5SA100 or the OP5110 treatment groups and commenced Period 1 for 4 weeks. Following Period 1, participants crossed over to the other treatment group and

Study Feature	Description
	commenced Period 2 for 4 weeks. All participants continued to the Restricted Bolus phase (Period 3), during which all participants used the Omnipod 5 SA 2.0 System at a target of 100 mg/dL for an additional 4 to 6 weeks (depending on age group) with a goal of no more than 3 boluses per day.
Periods 1 and 2 (Crossover Phase) Endpoints	<u>Primary Safety Endpoints</u> The following primary safety endpoints were tested hierarchically for non-inferiority between the two treatment groups: • Percentage of time < 54 mg/dL (non-inferiority (NI) margin of 0.75%) • Percentage of time < 70 mg/dL (NI margin of 3.0%) • Percentage of time in range 70 – 180 mg/dL (NI margin of 3.0%) • Mean sensor glucose (NI margin of 8.0 mg/dL) <u>Additional Safety Endpoints</u> The following additional safety endpoints were tested for the Crossover phase (Periods 1 and 2): • Number of severe hypoglycemia (SH) events • Number of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS) events <u>Exploratory Endpoints</u> The following exploratory endpoints were tested for superiority between the two treatment groups except for total boluses per day, percentage total insulin as basal, and total daily insulin per kg: • Percentage of time in range 70 –180 mg/dL • Mean sensor glucose • Percentage of time > 180 mg/dL • Percentage of time > 250 mg/dL • Percentage of time > 300 mg/dL • Percentage of time in range 70 –140 mg/dL • Total boluses per day (no formal testing) • Percentage total insulin as basal (no formal testing) • Total daily insulin per kg (no formal testing)
Period 3 (Restricted Bolus Phase) Endpoints	<u>Safety Endpoints</u> The following safety endpoints were tested for non-inferiority for the Restricted Bolus phase (Period 3) versus the treatment groups from the Crossover phase (Periods 1 and 2): • Percentage of time < 54 mg/dL (NI margin of 0.75%) • Percentage of time < 70 mg/dL (NI margin of 3.0%) <u>Additional Safety Endpoints</u> The following additional safety endpoints were tested for the Restricted Bolus phase (Period 3): • Number of SH events

Study Feature	Description
	• Number of DKA or HHS events Exploratory Endpoints The following exploratory endpoints were tested for superiority, except for total boluses per day, percentage total insulin as basal, and total daily insulin per kg, for Period 3 compared with the two treatment groups from Periods 1 and 2: • Percentage of time in range 70 –180 mg/dL • Mean sensor glucose • Percentage of time > 180 mg/dL • Percentage of time > 250 mg/dL • Percentage of time > 300 mg/dL • Percentage of time in range 70 –140 mg/dL • Total boluses per day (no formal testing) • Percentage total insulin as basal (no formal testing) Total daily insulin per kg (no formal testing)
Breakdown of subjects	• 136 participants were screened • 132 were randomized and started Period 1; 131 completed Period 1 (1 T1D 3 yrs dropped during Period 1) • 131 started Period 2 and 130 completed Period 2 (1 T1D 16 yrs was unable to complete visits, but had sufficient data for crossover analysis) • 128 started and completed Period 3 (1 T1D 2 yrs and 1 T1D 16 yrs dropped before Period 3)
Safety Results	There were no reports of SH, DKA or HHS, and there were also no deaths, unanticipated adverse device effects, serious adverse device effects or serious adverse events during the Crossover phase and during the Restricted Bolus phase.

Participant Demographics (N = 132 subjects at Randomization)

	T1D (N=98)	T2D (N=34)	Overall (N=132)
Age (yrs) - *n (%)*			
2-<6	29 (30%)	0	29 (22%)
6-<14	36 (37%)	0	36 (27%)
14-<22	6 (6%)	0	6 (5%)
22 and over	27 (28%)	34 (100%)	61 (46%)
Mean (SD)	19 (18)	56 (9)	28 (23)
Range	2 to 67	23 to 70	2 to 70
Sex – Female – *n (%)*	57 (58%)	20 (59%)	77 (58%)
Weight (kg) - Mean (SD)	50 (27)	101 (32)	63 (36)
BMI – *n (%)*			

	T1D (N=98)	T2D (N=34)	Overall (N=132)
<18.5	38 (39%)	0	38 (29%)
18.5-<25	34 (35%)	4 (12%)	38 (29%)
25-<30	15 (15%)	9 (26%)	24 (18%)
≥30	11 (11%)	21 (62%)	32 (24%)
Mean (SD) (kg/m^2)	22 (6)	35 (10)	25 (9)
Range (kg/m^2)	15 to 44	21 to 72	15 to 72
Race– *n (%)* or *n*			
American Indian/Alaskan Native	0	0	0
Asian	0	0	0
Black/African-American	6 (6%)	6 (18%)	12 (9%)
More than one race	4 (4%)	1 (3%)	5 (4%)
Native Hawaiian/Other Pacific Islander	0	0	0
White	86 (88%)	27 (79%)	113 (86%)
Unknown/ not reported	2 (2%)	0	2 (2%)
Ethnicity – *n (%)*			
Hispanic	8 (8%)	13 (38%)	21 (16%)
Non-Hispanic	90 (92%)	20 (59%)	110 (83%)
Unknown/not reported	0	1 (3%)	1 (<1%)
Race/Ethnicity – *n (%)*			
White non-Hispanic	79 (81%)	14 (41%)	93 (70%)
Black non-Hispanic	6 (6%)	5 (15%)	11 (8%)
Hispanic	8 (8%)	13 (38%)	21 (16%)
Other races and ethnicities	5 (5%)	2 (6%)	7 (5%)
Education – *n (%)*			
High school / GED or less	21 (21%)	14 (41%)	35 (27%)
Technical/vocational/associate	10 (10%)	8 (24%)	18 (14%)
College Graduate (Bachelor's or equiv.)	29 (30%)	6 (18%)	35 (27%)
Advanced Degree	37 (38%)	4 (12%)	41 (31%)
Do not wish to provide/NA	1 (1%)	2 (6%)	3 (2%)
Annual Household Income – *n (%)*			
<$50,000/year	5 (5%)	10 (29%)	15 (11%)
$50,000-<$100,000/year	11 (11%)	7 (21%)	18 (14%)
$100,000-<$200,000/year	37 (38%)	10 (29%)	47 (36%)
≥$200,000/year	35 (36%)	4 (12%)	39 (30%)

	T1D (N=98)	T2D (N=34)	Overall (N=132)
Unknown/NA	10 (10%)	3 (9%)	13 (10%)
Health Insurance – *n (%)*			
Private	85 (87%)	22 (65%)	107 (81%)
Other	13 (13%)	12 (35%)	25 (19%)

* For participants <18yrs, this is referring to parental education.

Participant Characteristics – Diabetes by Type and Age (N = 132 subjects at Randomization)

	T1D (N=98)	T2D (N=34)	Overall (N=132)
Diabetes Duration - *n (%)*			
<5yrs	45 (46%)	1 (3%)	46 (35%)
5-<10 yrs	25 (26%)	2 (6%)	27 (20%)
10-<20 yrs	11 (11%)	13 (38%)	24 (18%)
≥20 yrs	17 (17%)	18 (53%)	35 (27%)
Median (IQR) - *yrs*	6 (3, 13)	21 (14, 25)	9 (3, 22)
Range - *yr*	1 to 61	4 to 33	1 to 61
Non-Insulin Medications - *n (%)*			
GLP1	6 (6%)	23 (68%)	29 (22%)
SGLT2	0	14 (41%)	14 (11%)
Metformin	1 (1%)	22 (65%)	23 (17%)
Both GLP1 and SGLT2	0	10 (29%)	10 (8%)
GLP1 only	6 (6%)	13 (38%)	19 (14%)
SGLT2 only	0	4 (12%)	4 (3%)
None	92 (94%)	7 (21%)	99 (75%)
Duration of Omnipod Use at Baseline - *n (%)*			
3-<6 months	5 (5%)	3 (9%)	8 (6%)
6 months-<1 year	11 (11%)	4 (12%)	15 (11%)
1-<2 years	22 (22%)	18 (53%)	40 (30%)
2-<5 years	53 (54%)	7 (21%)	60 (45%)
>= 5 years	7 (7%)	2 (6%)	9 (7%)
HbA1c - Local - *n (%)*			
<8.0%	87 (89%)	26 (76%)	113 (86%)
8.0%-<9.0%	10 (10%)	7 (21%)	17 (13%)
≥9.0%	1 (1%)	1 (3%)	2 (2%)
Mean (SD) - %	6.9 (0.8)	7.3 (0.8)	7.0 (0.8)

	T1D (N=98)	T2D (N=34)	Overall (N=132)
Range - %	4.9 to 9.2	5.5 to 9.4	4.9 to 9.4
Total Daily Insulin (U/kg/day)			
Mean (SD)	0.8 (0.3)	0.6 (0.2)	0.7 (0.3)
Range	0.1 to 1.7	0.2 to 1.1	0.1 to 1.7
Total Daily Insulin (U/day)			
Mean (SD)	39 (27)	58 (28)	44 (28)
Range	9 to 147	18 to 123	9 to 147
SH ever - *n (%)*	14 (14%)	4 (12%)	18 (14%)
DKA ever - *n (%)*	32 (33%)	0	32 (24%)
HHS ever - *n (%)*	0	0	0

Crossover Phase Results

The primary safety endpoints in the crossover phase were tested hierarchically for non-inferiority between the two treatment groups (OP5SA100 versus OP5110) during the Crossover phase (Periods 1 and 2). The non-inferiority results are summarized below: pooled results across diabetes type and age, percentage of time < 54 mg/dL by diabetes type and age, and percentage of time < 70 mg/dL by diabetes type and age.

Primary Safety Endpoints: Non-inferiority Pooled Across Diabetes Type and Age

	Baseline (N=132)	OP5110 (N=132)	OP5SA100 (N=131)	Mean Estimate and 95% CI for OP5SA100 vs. OP5110	NI	P-Value for NI OP5SA100 vs. OP5110*$
Non-inferiority in % below 54 mg/dL (NI=0.75%) - *mean (SD)^*	0.29% (0.31%)	0.30% (0.30%)	0.34% (0.30%)	0.04% (-∞, 0.11%)	0.75%	<0.001
Non-inferiority in % below 70 mg/dL (NI=3.0%) - *mean (SD)^*	1.60% (1.37%)	1.66% (1.30%)	2.02% (1.47%)	0.37% (-∞, 0.56%)	3.0%	<0.001
Non-inferiority in % in range 70-180 mg/dL (NI=3.0%) - *mean (SD)*	66% (15%)	70% (13%)	73% (12%)	2.9% (1.9%, +∞)	-3.0%	<0.001
Non-inferiority in mean sensor glucose (NI=8 mg/dL) - *mean (SD)*	165 (27)	158 (20)	151 (18)	-7 (-∞, -6)	8 mg/dL	<0.001

*P-values tested hierarchically, and the process stopped at the first P-value ≥0.05. A repeated measures linear regression that controlled for period effect and accounted for the baseline values was used.
^Winsorized Mean and SD; values below 10th and above 90th percentiles were winsorized.

$A test for carry-over effect was done and it was not statistically significant for any of the four primary safety endpoints. Additionally, treatment group interactions with type and age were done for percentage time below 54 and 70 mg/dL and none were statistically significant.

Primary Safety Endpoint: Non-inferiority in Percentage of Time Below 54 mg/dL (NI = 0.75%) by Diabetes Type and Age

	Baseline *mean (SD)*^ **(N=132)**	**OP5110** *mean (SD)*^ **(N=132)**	**OP5SA100** *mean (SD)*^ **(N=131)**
P-value for Treatment Group Interaction with Type = 0.30			
Type 1	0.35% (0.31%)	0.38% (0.30%)	0.40% (0.30%)
Type 2	0.14% (0.24%)	0.08% (0.12%)	0.15% (0.21%)
Type 1 Only: P-value for Treatment Group Interaction with Age = 0.48			
Age 2-<6 yrs	0.42% (0.35%)	0.47% (0.34%)	0.48% (0.32%)
Age 6-<14 yrs	0.33% (0.27%)	0.36% (0.26%)	0.41% (0.30%)
Age ≥14 yrs	0.22% (0.29%)	0.20% (0.26%)	0.25% (0.25%)
P-value for Treatment Group Interaction with Age (14-<22 vs. ≥22-70) = 0.75			
Age 14-<22 yrs	0.30% (0.29%)	0.23% (0.12%)	0.29% (0.22%)
Age ≥22-70 yrs	0.21% (0.27%)	0.19% (0.25%)	0.22% (0.22%)

^Winsorized Mean and SD

Primary Safety Endpoint: Non-inferiority in Percentage of Time Below 70 mg/dL (NI=3.0%) by Diabetes Type and Age

	Baseline *mean (SD)*^ **(N=132)**	**OP5110** *mean (SD)*^ **(N=132)**	**OP5SA100** *mean (SD)*^ **(N=131)**
P-value for Treatment Group Interaction with Type = 0.21			
Type 1	1.97% (1.35%)	2.09% (1.22%)	2.50% (1.35%)
Type 2	0.55% (0.77%)	0.42% (0.47%)	0.65% (0.77%)
Type 1 only: P-value for Treatment Group Interaction with Age = 0.28			
Age 2-<6 yrs	2.27% (1.41%)	2.45% (1.30%)	2.78% (1.34%)
Age 6-<14 yrs	2.07% (1.35%)	2.01% (1.14%)	2.67% (1.40%)
Age ≥14 yrs	1.06% (1.15%)	1.13% (1.15%)	1.34% (1.24%)
P-value for Treatment Group Interaction with Age (14-<22 vs. ≥22-70) = 0.82			
Age 14-<22 yrs	1.28% (1.07%)	1.56% (0.55%)	1.55% (0.7%)
Age ≥22-70 yrs	0.92% (0.91%)	1.00% (1.01%)	1.25% (1.16%)

^Winsorized Mean and SD

Restricted Bolus Phase Results

The Table below presents the non-inferiority analysis of the 2 safety endpoints for the Restricted Bolus phase (Period 3) compared with the OP5110 group from the Crossover phase (Periods 1 and 2).

Safety Endpoints for Restricted Bolus Phase (Period 3)

	Baseline (N=132)	**OP5110 (N=132)**	**OP5SA100 (N=131)**	**Restricted Bolus (N=128)**	**Mean Estimate and 95% CI for Restricted Bolus vs. OP5110**	**NI**	**P-Value for NI Restricted Bolus vs. OP5110***
Non-inferiority in % below 54 mg/dL (NI=0.75%) - *mean (SD)^*	0.29% (0.31%)	0.30% (0.30%)	0.34% (0.30%)	0.41% (0.39%)	0.11% (-∞, 0.18%)	0.75%	<0.001
Non-inferiority in % below 70 mg/dL (NI=3.0%) - *mean (SD)^*	1.60% (1.37%)	1.66% (1.30%)	2.02% (1.47%)	2.08% (1.50%)	0.44% (-∞, 0.65%)	3.0%	<0.001

*P-values tested hierarchically, and the process stops at the first P-value ≥0.05. A repeated measures linear regression that control for period effect and accounts for the baseline values was used.
^Winsorized Mean and SD; values below 10th and above 90th percentiles were winsorized.

Split factor during the restricted bolus phase (period 3):

- 71/128 users (55.4%) used the device with a time-weighted average split factor between 50-60%,
- 38/128 users (29.7%) used the device with a time-weighted average split factor between 60-70%,
- 19/128 users (14.8%) used the device with a time-weighted average split factor between 70-75%,
- 40/128 users (31.3%) utilized at least one pod with a split factor over 70%,
- 21/128 users (16.4%) reached the maximum split factor of 75% at least once over the last 3 pod wears (~9 days).

C. Other Supportive Device Performance Characteristics Data

Software

Information on software of the device was reviewed and found to be acceptable. Software Verification and Validation activities were performed in accordance with IEC 62304 and FDA's guidance "*General Principles of Software Validation.*" Software documentation was provided in accordance with FDA guidance "*Content of Premarket Submissions for Device Software Functions*".

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.