January 27, 2022

Insulet Corporation
Katie Pacheco
Director of Regulatory Affairs, Digital Health
100 Nagog Park
Acton, MA 01720

Re: K203774
Trade/Device Name: SmartAdjust technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJI
Dated: September 2, 2021
Received: September 3, 2021

Dear Katie Pacheco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203774

Device Name
SmartAdjust technology

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Insulet Corporation

510(K) SUMMARY

Date Prepared:	January 26, 2022
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park, Acton, MA, 01720
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3014585508
Contact Person: **Phone:** **Fax:**	Katie Pacheco Director, Regulatory Affairs, Digital Health 978 932 0027 978 600 0120
Device Trade/Proprietary Name:	SmartAdjust technology
Device Common Name:	Omnipod 5 iAGC
Regulation Description	Interoperable Automated Glycemic Controller
Review Panel(s):	Clinical Chemistry
Product Code(s):	QJI
Regulation Numbers:	21 CFR 862.1356
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	K200467, Control-IQ Technology

Device Description:

The Omnipod 5 iAGC (SmartAdjust technology) 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 suspend the delivery of insulin via a compatible alternate controller enabled (ACE) pump.

The Omnipod 5 iAGC software is part of the Omnipod 5 Automated Insulin Delivery System, which also includes the Omnipod 5 ACE Pump, Omnipod 5 Bolus Calculator, and an interoperable iCGM. The Omnipod 5 iAGC is intended to be digitally connected to an iCGM and an ACE Pump.

The Omnipod 5 iAGC 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 Omnipod 5 iAGC uses this transmitted iCGM data in its calculations. The Omnipod 5 iAGC can be turned off, and the Omnipod 5 ACE Pump will operate in Manual Mode, which delivers insulin based on HCP- or user-defined Basal Programs.

The Omnipod 5 iAGC 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 Omnipod 5 iAGC 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 Omnipod 5 iAGC will resume delivery of insulin in full Automated Mode. Activity is a user-selected temporary feature intended for use during periods when insulin sensitivity is expected to be higher, such as during exercise. With Activity, the algorithm reduces insulin delivery and sets a temporary glucose target of 150 mg/dL.

Summary of Technological Characteristics Compared to Predicate Device:

The subject device and predicate device use similar operating principles to achieve the intended therapeutic effect. The subject device has the same intended use and similar indications for use, principles of operation, and use environment as the predicate device. The subject device and predicate device are both interoperable automated glycemic controllers that integrate with compatible integrated continuous glucose monitors (iCGM) and ACE Pumps to automatically increase, decrease, and suspend the delivery of insulin based on iCGM data and predicted glucose readings.

The differences between predicate and subject device include the glucose targets, device(s) that host the controller, compatible bolus calculator, and alarm features/functionality. The differences do not raise different questions about safety and effectiveness and the performance data, human factors validation, and clinical data demonstrate the Omnipod 5 iAGC is substantially equivalent to its predicate device. **Table 1** below illustrates the equivalence of the subject device to the predicate.

Table 1. Substantial Equivalence Comparison

Element of Comparison	Subject Device: Omnipod 5 Interoperable Automated Glycemic Controller (iAGC)	Predicate Device: Tandem Diabetes Care, Inc. Control-IQ Technology (K200467)

Element of Comparison	Subject Device: Omnipod 5 Interoperable Automated Glycemic Controller (iAGC)	Predicate Device: Tandem Diabetes Care, Inc. Control-IQTechnology (K200467)
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 6 years of age and older. SmartAdjust technology is intended for single patient use and requires a prescription.	Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 6 years of age and greater. Control-IQ technology is intended for single patient use and requires a prescription. Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.
Age Range of Intended Users	Ages 6 and older	Ages 6 and older
Environment of use	Ambulatory use	Ambulatory use
Specific Drug/Biologic Use	U-100 Insulin System has been tested with NovoLog®, Humalog®, and Admelog®	U-100 Insulin System has been tested with NovoLog® and Humalog®
Prescription Status	Prescription Device	Prescription Device
Principles of Operation	Algorithmic software device intended to automatically increase, decrease, and suspend delivery of insulin based on iCGM readings and predicted glucose values	Algorithmic software device intended to automatically increase,decrease, and suspend delivery ofinsulin based on iCGM readings and predicted glucose values

Labeling	Package Labels, User's Guide (contains Instructions for Use), Quick Start Guide	Package Labels, User's Guide (contains Instructions for Use)
Communication andPairing	Bluetooth Low Energy (BLE) wireless technology	Bluetooth Low Energy (BLE) wireless technology
Device Hosting Controller	Omnipod 5 ACE Pump	T:slim X2 insulin pump
Digitally Connected Devices	Cleared iCGM and ACE Pump, which includes an Android OS display device (Insulet-provided Controller phone or user's compatible smartphone)	Cleared iCGM and ACE Pump
System Functionality Modes	• SmartAdjust technology enabled - Automated Mode (closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values) • SmartAdjust technology not enabled - Manual Mode (open loop, basal delivery based on user-defined programs)	• Control IQ technology enabled (closed loop, automatically increase, decrease, and suspenddelivery of insulin based on iCGM readings and predicted glucose values. Can deliver automatic correction bolus when glucose value is predicted to exceed a predefined threshold). • Control IQ technology not enabled (open loop, basal delivery based on user defined programs)
Alarms/Alerts	Out of Range Alert Low Alert Maximum Insulin/Delivery Alert	Out of Range Alert Low Alert High Alert Maximum Insulin/Delivery Alert
Alert/Alarm Display	ACE Pump alarms/alerts will be displayed and communicated tothe user via visual, audible, and/or vibratory cues.	ACE Pump alarms/alerts will bedisplayed and communicated tothe user via visual, audible, and/or vibratory cues.
Mechanism of Software Update	Firmware over the Air	Firmware over the Air
History Storage	Up to 90 days (user insulin history)	At least 90 days
Target Glucose Control Range	110-150 mg/dl, user-customizable	112.50-160 mg/dl, not user-customizable

Standards Compliance

The Omnipod 5 iAGC complies with the following standards as documented in the applicable test reports provided in this 510(k) submission.

- IEC 62366:2015 – Medical Devices – Part 1: Application of Usability Engineering
- HE75:2009 – Human Factors Engineering – Design of Medical Devices
- ISO 14971:2007 – Medical devices – Application of Risk Management to Medical Devices
- IEC 62304 Ed. 1.1 2015 – Medical device software – Software life cycle processes
- ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good clinical practice

Summary of Non-Clinical Performance Data

The information presented in this 510(k) demonstrates the safety and effectiveness of the Omnipod 5 iAGC with a compatible ACE Pump and iCGM. Performance testing with the Omnipod 5 iAGC included the following:

- **Risk Management:** Risk management was completed in accordance with ISO 14971:2007. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the devices are safe for use.
- **Human Factors Validation:** Insulet executed a comprehensive human factors and usability engineering process that followed and complied with the FDA-recognized standards IEC 62366:2015-1 and HE75:2009 as well as the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices – Issued February 3, 2016. A robust validation evaluation was performed to demonstrate safe and effective use of the Omnipod 5 iAGC with intended users in the expected use environments, including associated training and accompanying documentation. The results of the validation demonstrate that the iAGC has been found to be safe and effective for the intended users, uses, and use environments.
- **Software Validation:** Software verification and validation testing was performed in accordance with IEC 62304:2015 and FDA's guidance document, General Principles of Software Validation – Issued January 11, 2002.

- **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.
- **Interoperability**: Interoperability documentation was 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 – Issued September 6, 2017 and specifies validated interface specifications to potential interoperable devices and partnership agreements regarding contractual issues, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities.
- **Cybersecurity:** A cybersecurity analysis was performed for the Omnipod 5 iAGC using the FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical devices – Issued October 18, 2020, and the principles outlined in the FDA guidance, Postmarket Management of Cybersecurity in Medical Devices, – Issued December 28, 2020. Insulet has provided a software bill of materials and penetration testing.
- **Special Controls:** Evaluation of the Special Controls for this device (regulation 21 CFR 862.1356) assures the safety and effectiveness of the device.

Summary of Clinical Performance Data

A clinical study was performed with the Omnipod 5 iAGC per ISO 14155:2011 with the objective to assess the safety and effectiveness of the system. This single-arm, multicenter, prospective study enrolled 240 subjects – 112 children (6 to 13.9 years) and 128 adolescents and adults (14 to 70 years). A 2-week standard therapy phase (usual insulin regimen) was followed by 3 months of the Omnipod 5 System use in Automated Mode. Upon completion of the 3-month phase, subjects continued into an optional Automated Mode extension, which is currently ongoing. The primary effectiveness analysis consisted of A1C and sensor glucose time in range (70-180 mg/dL) results. The primary safety endpoints included the incidence of severe hypoglycemia and diabetic ketoacidosis (DKA). An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary, secondary, and safety results is presented in the tables below.

Of the 240 subjects enrolled across 17 investigational sites, 98% completed the 3-month Omnipod 5 phase of the trial (111 children and 124 adolescents and adults). The study

population consisted of people with type 1 diabetes for at least 6 months. All subjects were required to have an A1C < 10.0% at screening. Key exclusion criteria included: taking oral or injectable steroids or diabetes medications other than metformin and insulin; history of severe hypoglycemia or DKA in the past 6 months; and history of cardiovascular disease. Select baseline characteristics of the subjects at the start of the 3-month Omnipod 5 treatment phase are provided in the table below.

Baseline Characteristics at Omnipod 5 Treatment Phase Initiation (N=240)

Characteristic	Children (6 to 13.9 years)	Adolescents & Adults (14 to 70 years)
N	112	128
Age (years) ± SD	10.3 ± 2.2	36.9 ± 13.9
A1C§	7.67% ± 0.95%	7.16% ± 0.86%
Multiple daily injections as Standard Therapy, n (%)	13 (11.6%)	20 (15.6%)

Plus-minus values are average ±standard deviation (SD)

§ Glycated hemoglobin determined from laboratory assessment.

Glycemic 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. Children, adolescents, and adults experienced improvements in overall A1C and time in range after 3 months of Omnipod 5 System use. This was achieved with a reduction of time >180 mg/dL in adolescents, adults, and children as well as a reduction in median time <70 mg/dL in adolescents and adults.

Glycemic 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 A1C, % (std dev)	7.67% (0.95%)	6.99% (0.63%)	-0.71%*	7.16% (0.86%)	6.78% (0.68%)	-0.38%*
Avg sensor glucose, mg/dL (std dev)	183 (32)	160 (15)	-23*	161 (28)	154 (17)	-8*
Percentage Time in Glucose Range						
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%*
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%*

**Change between standard therapy phase and Omnipod 5 System phase was significant (P < 0.0001).*

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

Characteristic	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70years) (n=128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Percentage time in glucose range, %						
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%*
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%*

**Change between standard therapy phase and Omnipod 5 System phase was significant (P < 0.0001).*

Safety Results

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 adolescents/adults).

Adverse Events during the Omnipod 5 Treatment Phase

Adverse Event Type	Children (6 to 13.9 years) (n=112)	Adolescents & Adults (14 to 70 years) (n=128)	Total (6 to 70 years) (N=240)
Primary Safety Endpoints (events per person-month)			
Severe hypoglycemia	0.003	0.005	0.004
Diabetic ketoacidosis	0.003	0.000	0.001
Hypoglycemia ‡	1 (0.9%)	0 (0.0%)	1 (0.4%)
Severe Hypoglycemia §	1 (0.9%)	2 (1.6%)	3 (1.3%)
DKA	1 (0.9%)	0 (0.0%)	1 (0.4%)
Hyperglycemia ‖	1 (0.9%)	2 (1.6%)	3 (1.3%)
Prolonged Hyperglycemia **	13 (10.7%)	5 (3.1%)	18 (6.7%)
Other	8 (7.1%)	8 (6.3%)	16 (6.7%)

Results reported with number in brackets afterwards represent number of events (% of subjects).

‡ 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*

Substantial Equivalence Conclusion

The Omnipod 5 iAGC has the same intended use and similar indications for use as the predicate device and is intended to be used in the same environment as the predicate device. While there are minor differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions about safety and effectiveness.

The non-clinical and clinical performance data described above supports the determination of substantial equivalence to the predicate device. This data demonstrates sufficient implementation of design considerations relative to data logging, interoperability, and cybersecurity design as required by the Special Controls for this device (regulation 21 CFR 862.1356). Human factors and clinical validation successfully demonstrate that the Omnipod 5 iAGC has been found to be safe and effective for the intended users, uses, and use environments. Therefore, the Omnipod 5 iAGC is substantially equivalent to the predicate device.