510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K203768

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod 5 ACE Pump (Pod)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump	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.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Indication(s) for Use:

The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Omnipod 5 ACE Pump is intended for single patient, home use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Omnipod 5 System is NOT recommended for people who:

- are unable to monitor glucose as recommended by their healthcare provider
- are unable to maintain contact with their healthcare provider
- are unable to use the Omnipod 5 System according to instructions
- 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 have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and remindersThe Pod must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.

The Omnipod 5 ACE Pump (Pod) is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

IV Device/System Characteristics:

A Device Description:

The Omnipod 5 (OP5) ACE Pump is a wearable, tubeless insulin pump intended to be used with a compatible controller such as an interoperable automated glycemic controller (iAGC) for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The OP5 ACE Pump is a component of the OP5 System, which also includes the OP5 Application ("App").

The OP5 ACE Pump (may also be called "OP5 Pod" or "Pod" for the body-worn physical component implementing the ACE Pump functionality) pairs through secure Bluetooth technology and can only be paired with one controller for its use life (up to 80 hours). The ACE Pump sends delivery confirmation, state information, and alarms and alerts to the compatible App/controller. Data logging is performed by the Pod components and App, where insulin delivery history is viewable through the App/controller software.

The OP5 Pod is identical to the predicate Omnipod DASH System Pod (K191679) except for having additional electronic hardware components on the printed circuit board assembly (PCBA), new battery/power supply, and additional modules of software.

The OP5 Pod is a small, lightweight, single-use, sterilized device designed to attach to the body via an adhesive pad that is heat-staked to the bottom of the Pod. The Pod's adhesive backing keeps it in place for up to 3 days and is applied to areas with a layer of fatty tissue including the abdomen, hip, back of upper arm, upper thigh, or lower back. When used with an interoperable continuous glucose monitor (iCGM), the Pod should be placed within line-of-sight of the CGM. Once removed, the Pod cannot be reapplied.

The Pod includes an insulin reservoir that can be filled with 85 – 200 units of compatible U-100 rapid-acting insulin. Insulin is delivered through a soft cannula that is automatically inserted into the subcutaneous tissue by the Pod. The Pod is waterproof to 25 feet (7.6 meters) for up to 60 minutes. The Pod housing includes a viewing window at the insertion site for checking proper cannula placement and integrity.

B Instrument Description Information:

1. Instrument Name:

   Omnipod 5 ACE Pump (Pod)

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):
Omnipod DASH Insulin Management System with interoperable technology

B Predicate 510(k) Number(s):
K191679

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203768	K191679
Device Trade Name	Omnipod 5 ACE Pump (Pod)	Omnipod DASH™ Insulin Management System
General Device Characteristic Similarities		
Indications For Use	The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. (It) is intended for single patient, home use and requires a prescription.	Same
General Device Characteristic Differences		
Controller Device	Controlled by the Omnipod 5 App	Controlled by DASH PDM

VI Standards/Guidance Documents Referenced:

- 21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump (Special Controls).
- IEC 60601-2-24:2012 Ed. 2.0, Medical Electrical Equipment, Basic Safety and Essential Performance of infusion pumps and controllers
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0: 2014: Medical Electrical Equipment- Part 1-2: Collateral Standard: Electromagnetic Disturbances- Requirements and Tests in accordance
- IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8 Edition 2.1: 2012: Medical Electrical Equipment- Part 1-8: Collateral Standard: Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- 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
- IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- ISO 10993-1: 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Cytotoxicity study using the ISO direct contact method
- ISO 10993-12: 2012 Biological evaluation of medical devices – Part 12: Sample preparation of reference materials
- ISO 10993-17: 2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18: 2020 Biological evaluation of medical devices – Part 18: Chemical characterization of materials
- AAMI/ANSI/ISO 11135: 2014 Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- AAMI TIR 28:2016 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
- FDA Guidance "Design Considerations and Premarket Submission - Recommendations for Interoperable Medical Devices" dated September 6, 2017FDA Guidance "Infusion Pumps Total Product Life Cycle" dated December 2, 2014
- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016
- FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005
- FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" dated October 2, 2014

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Accuracy (Instrument):

Accuracy for basal delivery, bolus delivery, and occlusion detection were evaluated and confirmed to be acceptable.

Basal Delivery:

In order to assess basal delivery accuracy, 12 Pods were tested by delivering at low, medium, and high basal rates (0.05, 1.00, and 30.0 U/hr). Water was used as a substitute for insulin. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warm-up period. For each time period, the tables show the volume of

insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.05 U/hr)			
Basal Duration (Number of units requested	1 hour (0.05 U)	6 hours (0.30 U)	12 hours (0.60 U)
Amount Delivered	0.049 U	0.30 U	0.59 U
[min, max]	[0.00, 0.12]	[0.13, 0.57]	[0.34, 0.99]

Medium Basal Rate Delivery Performance (1.00 U/hr)			
Basal Duration (Number of units requested	1 hour (1.00 U)	6 hours (6.00 U)	12 hours (12.00 U)
Amount Delivered	0.99 U	5.97 U	11.88 U
[min, max]	[0.65, 1.55]	[5.06, 6.87]	[10.53, 13.26]

High Basal Rate Delivery Performance (30.00 U/hr)		
Basal Duration (Number of units requested	1 hour (30.00 U)	6 hours (180.00 U)
Amount Delivered	29.82 U	179.33 U
[min, max]	[28.85, 31.39]	[177.49, 181.15]

Note: A measurement at the 12-hour period with a 30.0 U/hr basal rate is not applicable to the Omnipod 5 System as the reservoir will empty at approximately 6.67 hours at this rate.

Bolus Delivery:

In order to assess bolus delivery accuracy, 12 Pods were tested by delivering a minimum, intermediate, and maximum bolus amount (0.05, 5.00, and 30.0 Units). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid delivered was used to assess pumping accuracy.

The following table summarizes the typical bolus performance observed for the requested minimum, intermediate, and maximum size bolus for all pumps tested. For each individual target bolus size, the number of boluses observed is shown along with the average (mean), minimum, and maximum units delivered as measured by a scale.

Individual Bolus Accuracy Performance	Target Bolus Size (Units)	Mean Bolus Size (Units)	Min Bolus Size (Units)	Max Bolus Size (Units)
Min Bolus Delivery Performance (n = 5987 boluses)	0.05 U	0.050 U	0.00 U	0.119 U
Intermediate Bolus Delivery Performance (n = 300 boluses)	5.00 U	5.01 U	4.49 U	5.37 U
Max Bolus Delivery Performance (n = 72 boluses)	30.00 U	30.05 U	29.56 U	30.62 U

The tables below show for each requested bolus size, the range of amount of insulin that was observed delivered compared to the requested amount. Each table provides the number and percent of delivered bolus sizes observed within the specified range.

Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request

Amount (Units)	<0.0125	0.0125-0.0375	0.0375- 0.045	0.045-0.0475	0.0475-0.0525
(% of settings)	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
Number and percent of boluses within range	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)
Amount (Units)	0.0525-0.055	0.055-0.0625	0.0625-0.0875	0.0875-0.125	>0.125
(% of settings)	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
Number and percent of boluses within range	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

Amount of Insulin Delivery for an Intermediate (5.00 U) Bolus Request

Amount (Units)	<1.25	1.25- 3.75	3.75- 4.50	4.50-4.75	4.75- 5.25
(% of settings)	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
Number and percent of boluses within range	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)
Amount (Units)	5.25-5.5	5.5-6.25	6.25- 8.75	8.75-12.50	>12.50
(% of settings)	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
Number and percent of boluses within range	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

Amount of Insulin Delivery for a Maximum (30.00 U) Bolus Request

Amount (Units) (% of settings)	7.5 (<25%)	7.5-22.5 (25-75%)	22.5-27.0 (75-90%)	27.0-28.5 (90-95%)	28.5-31.5 (95-105%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units) (% of settings)	31.5-33.0 (105-110%)	33.0-37.5 (110-125%)	37.5-52.5 (125-175%)	52.5-75.0 (175-250%)	>75.0 (>250%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

Occlusion (Blockage) Detection:

Occlusion detection testing was conducted using 60 pumps. To test the time between occlusion and pump alarm, pumps were physically blocked. To test the time to a blockage alarm during a bolus and basal delivery, a range of insulin delivery values were programmed. Log files from the devices were downloaded once the pumps triggered a blockage alarm to gather data for the times when the pump was blocked and when the pump reported it triggered the alarm. The typical time for a 5-unit bolus is the upper most allowable bound for the samples and the maximum time is the absolute maximum. All samples tested met performance that is presented in the table below.

	Typical time to Blockage Alarm	**Maximum time to Blockage Alarm**
5.0 U Bolus	33 minutes	35 minutes
1.0 U/hr Basal	3.0 hours	5.5 hours
0.05 U/hr Basal	51 hours	80 hours (Pod expiration)

B Other Supportive Instrument Performance Characteristics Data:

a. Clinical Testing:
Two clinical studies were conducted in subjects 6-70 years of age, with type 1 diabetes to evaluate the Omnipod 5 System, of which the Omnipod 5 ACE pump is a component. These studies are described in the Decision Summary for K203774 and demonstrate that the Omnipod 5 ACE pump functions as intended.

b. Human Factors:
Human Factors validation tests were conducted on the Omnipod 5 System and described in more detail in the Decision Summary for K203774.

c. Biocompatibility:

All patient-contacting materials and manufacturing processes of the Omnipod 5 ACE Pump (Pod) are the same as those of the currently marketed Omnipod DASH system. Therefore, previous biocompatibility testing of the predicate device is still applicable.

d. Sterility:
The sterilization procedure has not changed from the procedure established for the predicate device, K191679. For the subject device, a product adoption assessment was performed in accordance with AAMI TIR28:2016 Product adoption and process equivalence for ethylene oxide sterilization. The assessment indicated that the subject device is the same or similar to the existing family of devices, and therefore supports sterility of the patient contact components of the device.

e. Insulin Compatibility and Stability:
The Omnipod 5 ACE Pump (Pod) is designed to use the following rapid-acting U-100 insulins: NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro). The fluid-contacting materials of the Omnipod 5 ACE pump remain unchanged from the predicate.

f. Additional Bench Testing:

In addition to the performance testing described above, mechanical testing, simulated use testing, and other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified. Summaries for Reliability, Safety, and Verification testing follow:

Testing to Support System Reliability
Electrical Specification Testing
Hardware Control Testing
Real Time Clock Testing
BLE Carrier Frequency Accuracy Testing
Wire Drive Testing
RF Throughput Test Report
Design Visual Inspection
System Integration Testing

Testing to Support System Safety
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Suspend and Resume Testing

Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Suspend and Resume Testing
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing
Regression Analysis and Testing

g. Electromagnetic Compatibility and Wireless Coexistence:
Insulet performed EMC and wireless coexistence evaluations including testing to appropriate standards for EMC (IEC 60601-1-2:2014, CISPR 11) demonstrating that the device is immune at appropriate EMI exposure levels. Insulet also performed wireless coexistence testing consistent with ANSI C 63.27, RTCA/DO-160G, AIM 7351731 to demonstrate that the device will perform as expected in the home healthcare environment.

h. Basic Safety and Essential Performance (Electrical Safety):
Insulet performed testing to demonstrate compliance with basic safety and essential performance in accordance with IEC 60601-1, IEC 60601-1-8, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-2-24. The device complies with those standards.

i. 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.

j. 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 found to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, the plans covered Insulet's approach to working with third party manufacturers of digitally connected devices 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).

Insulet 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.

k. Cybersecurity:
Detailed information on cybersecurity of the device was reviewed and found to be acceptable. Insulet 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.

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.