Food and Drug Administration
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information

A 510(k) Number

K191679

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod DASH Insulin Management System with interoperable technology

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

E Purpose for Submission

This submission seeks changes to the indications for use for the previously cleared Omnipod DASH Insulin Management System (k180045). As an ACE pump, the device can reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute and confirm commands from these devices.

II Intended Use/Indications for Use

A Intended Use(s)

See Indications for Use below.

B Indication(s) for Use

The Omnipod DASH Insulin Management System (the Pump) with interoperable technology is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. The 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 Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog, Humalog, Admelog, or Apidra U-100 insulin.

C Special Conditions for Use Statements

This device is for prescription use only.

The Pod and Personal Diabetes Manager (PDM) may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove and dispose of your Pod and place your PDM outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

The Omnipod DASH System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoLog, Humalog, Admelog, or Apidra. NovoLog, Humalog, and Admelog are compatible with the Omnipod DASH System for use up to 72 hours (3 days). Apidra is compatible with the Omnipod DASH System for use up to 48 hours (2 days). Before using a different insulin with the Omnipod DASH 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.

III Device Description

The hardware and software of the device is identical to the device cleared under k182630.
The Omnipod DASH Insulet management system with interoperable technology is a body-worn, battery operated, rate programmable infusion pump designed for the subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. It is comprised of two primary components: the disposable insulin infusion pump (Pod), and an associated Bluetooth Low Energy (BLE) enabled remote controller. The Omnipod DASH System is provided with the DASH PDM, but future alternate controllers may be established. The PDM includes a wireless internet interface to allow for software updates.

The Pod is a body-wearable insulin pump that affixes to the user on the back of the arm, the lower back or abdomen, the thigh area, or any site that has a layer of fatty tissue available. It is held in place by an adhesive pad and provides up to three days of insulin before it is removed and replaced with a new Pod. The DASH PDM is a handheld device that controls the Pod. The user interfaces with the device system through the DASH PDM using a touch screen, similar to a smartphone, where they control basal and bolus delivery and various insulin program settings and calculations. The DASH PDM also has a food library to assist with carbohydrate

calculations, and it maintains several variables in a history log for the viewer to track their diabetes therapy. The device system is for prescription use only.

The remote control design of the Pod inherently enables connectivity to other interoperable controllers with new functionality. Capabilities can be built into compatible controllers to add functionality such as Automated Insulin Dosing (AID) systems. In this design, a controller may contain an algorithm and connect to an integrated continuous glucose monitoring (iCGM) system (21 CFR 862.1355). In such an integrated system, the AID controller would be responsible for coordinating the interoperable devices (Omnipod DASH and iCGM) in order to automate dosing. It would read the Pod for insulin delivery status, read the iCGM for the sensor value, compute an automated dose and then command the Pod to deliver the required insulin amount. For this automated delivery to occur, the Controller is required to be in range of the Pod. The Pod is designed to default back to the programmed basal rate in the case of extended loss of communication.

IV Substantial Equivalence Information

A Predicate Device Name(s)

t:slim X2 insulin pump with interoperable technology

B Predicate 510(k) Number(s)

DEN180058

C Comparison with Predicate(s)

Device & Predicate Device(s):	k191679	DEN180058
Device trade name	**Omnipod DASH Insulin Management System with interoperable technology**	**t:slim X2 insulin pump with interoperable technology**
General Device Characteristic Similarities		
Intended use/Indications for use	Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. Intended to be interoperable with connected devices	Same

	including CGMs and automated insulin dosing algorithms	
Communication	Bluetooth Low Energy	Same
Memory	90 days on average of insulin delivery, blood glucose results, carbohydrate intake, and alarm data.	Same
General Device Characteristic Differences		
Compatible drug products	Novolog, Humalog, Apidra, or Admelog U-100 Insulin	Novolog or Humalog U-100 Insulin
Pump design	Single-use on-body pump with wireless controller	Reusable pump with integrated controller
Administration sets and reservoir	Integrated reservoir and patient activated cannula insertion system	Disposable reservoir and disposable infusion sets.
User interface	Hand-held touchscreen locked mobile device	Integrated touchscreen on infusion pump
Flow rates and profiles	Basal: 0.05 – 30 units/hour in 0.05 unit increments Bolus: 0.05 – 30 units in 0.05 unit increments 12 basal profiles	Basal: 0.1 – 15 units/hour in 0.001 unit increments Bolus: 0.05 – 25 units in 0.01 unit increments 6 insulin delivery profiles (basal and bolus)
Maximum bolus flow rate	1.5 units / minute	2.97 units / minute

V Standards/Guidance Documents Referenced

- FDA 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
- FDA Guidance "General Principles of Software Validation" dated January 11, 2002

- ISO 10993-1:2009 (4th Edition) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-3:2014 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-4:2002(A-2006) Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-6:2007 Biological Evaluation of Medical Devices – Part 6: Test for Local Effects After Implantation
- ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO 14971 Second Edition 2007-03-01 Medical Devices – Application of Risk Management to Medical Devices
- IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Ed. 4.0 b: 2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances- Requirements and Tests
- IEC 60601-1-6 Ed. 3.1 b. 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8 Ed. 2.1 b: 2012 Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- IEC 60601-1-11 Issued: 2015/01/20 Ed.2 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 62304:2006 Medical Device Software – Software Life Cycle Processes
- IEC 62366-1 Ed. 1.0 Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices
- 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
- AAMI/ANSI ST 72:2011 Bacterial Endotoxins – Test Methods, Routine Monitoring and Alternatives to Batch Testing
- ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [including Amendment 1 (2014)]

VI Performance Characteristics

A Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy, 12 Omnipod pumps were tested by delivering insulin 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 basal delivery 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 warmup 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.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 30 U/hr (high) basal rate setting

30 U/hr Basal Duration	**1 hour**	**6 hours**
Total expected delivery volume	**30 U**	**180 U**
Median amount delivered [min, max]	29.8 U [28.9, 31.4]	179 U [177, 181]

Note: A measurement at the 12-hour period with 30.0 U/hr basal rate is not applicable to the DASH System as the reservoir will empty at approximately 6 ⅔ hours at this rate.

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 1 U/hr (medium) basal rate setting

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1 U**	**6 U**	**12 U**
Median amount delivered [min, max]	0.99 U [0.65, 1.55]	5.97 U [5.06, 6.87]	11.9 U [10.5, 13.3]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 0.05 U/hr (low) basal rate setting

0.05 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.05 U**	**0.3 U**	**0.6 U**
Median amount delivered [min, max]	0.049 U [0.00, 0.12]	0.30 U [0.13, 0.57]	0.59 U [0.34, 0.99]

2. Bolus delivery accuracy

To assess bolus delivery accuracy, 12 Omnipod pumps 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 number of total and consecutive boluses delivered in this testing for each delivery volume is described in Table 4 below:

Table 4: Summary of bolus testing protocol

Bolus size (units)	Number of pumps tested	Consecutive boluses per pump	Total boluses
0.05 units	12	500	6000
5.0 units	12	25	300
30 units	12	6	72

Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various times points was used to assess bolus delivery accuracy. The actual bolus volume delivered was compared to the expected bolus volume for minimum, intermediate, and maximum boluses. Tables 5-7 below show the number (and %) of boluses within the specified range of each target bolus volume.

Table 5: Amount of fluid delivered after a 0.05 U bolus request

Units delivered after a 0.05 U bolus request (% of commanded units)										
	<0.0125 (<25%)	0.0125 - 0.0375 (25-75%)	0.0375-0.045 (75-90%)	0.045-0.0475 (90-95%)	0.0475-0.0525 (95-105%)	0.0525-0.0550 (105-110%)	0.055-0.0625 (110-125%)	0.0625-0.0875 (125-175%)	0.0875-0.125 (175-250%)	>0.125 (>250%)
Number and percent of boluses	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

Table 6: Amount of fluid delivered after a 5.0 U bolus request

Units delivered after a 5.0 U bolus request (% of commanded units)										
	<1.25 (<25%)	1.25-3.75 (25-75%)	3.75-4.50 (75-90%)	4.50-4.75 (90-95%)	4.75-5.25 (95-105%)	5.25-5.50 (105-110%)	5.50-6.25 (110-125%)	6.25-8.75 (125-175%)	8.75-2.50 (175-250%)	>12.50 (>250%)
Number and percent of boluses	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

Table 7: Amount of fluid delivered after a 30 U bolus request

Units delivered after a 30 U bolus request (% of commanded units)										
	<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%)	31.5-33.0 (105-110%)	33-37.5 (110-125%)	37.5-52.5 (125-175%)	52.5-75.0 (175-250%)	>75.0 (>250%)
Number and percent of boluses	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

3. Occlusion detection

An occlusion hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts occlusion detection for three different situations when using U-100 insulin. For example, if the pod's cannula becomes occluded when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

Table 8: Timing of occlusion detection alarms

	Typical time to occlusion detection	**Maximum time to occlusion detection**
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)

Occlusion detection testing was conducted using 64 pumps. To test the time between occlusion and pump alarm, pumps were physically occluded and insulin delivery was activated. Log files from the PDM were downloaded once the pumps triggered an occlusion alarm to gather the time when the PDM sent the delivery command and when the pump reported it triggered the alarm. This was used to calculate the time between occlusion and pump alarm. The typical time is the average for the samples and the maximum time is the absolute maximum.

B Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

A comprehensive hazard analysis for this device was reviewed in k182630 and k180045, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump component of those systems were reviewed in those 510(k) submission. The sponsor provided a revised hazard analysis in this submission to account for the unique design elements, intended use, and risks of the Omnipod DASH Insulin Management System which had not been previously reviewed. In

particular, this revised hazard analysis accounted for the risks associated with interoperability between the device and other third party digital devices which met predefined criteria but were not specifically identified, including scenarios in which the device was put into an environment in which both compatible and incompatible digital devices attempted to communicate with the device and deliver commands. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors testing was performed with the Insulet-supplied PDM as the controller for the Pod under k180045. The user interface for the DASH Insulin Management System is identical to that in k180045. For future interoperable controllers with Omnipod DASH Pod as an alternate controller enabled pump, additional human factors testing will need to be completed.

3. Biocompatibility

All of the materials and manufacturing processes of the subject Omnipod DASH Insulin Management System with interoperable technology are identical to those of the currently marketed system found in k182630 (and also in k180045), therefore no additional biocompatibility testing was conducted with the subject device for this 510(k).

Verification testing completed in accordance with ISO 10993 – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity – Part 4: Selection of tests for interactions with blood – Part 5: Tests for in vitro cytotoxicity – Part 6: Tests for local effects after implantation – Part 10: Tests for irritation and skin sensitization – Part 11: Tests for systemic toxicity – Part 17: Establishment of allowable limits for leachable substances and Part 18: Chemical Characterizations of Materials.

4. Sterility

The subject device is identical to the currently marketed Omnipod DASH Insulin Management System (k182630). The sterilization and shelf life information has not changed from that which was submitted in k182630.

5. Insulin Compatibility and Stability

In vitro testing was performed to assess extractables and leachables and insulin compatibility with Humalog, Novolog, Apidra, and Admelog U-100 insulin drugs. To support the compatibility of these insulin analogs the stability of these drugs was evaluated under stressed, worst-case conditions. The studies observed acceptable results of degradation

products, extractables, and leachables, and support the compatibility with these insulin analogs.

6. 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-
Occlusion Detection Testing
Suspend and Resume Testing
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
BGM Functions Testing
Insulin Delivery Verification Testing

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-
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

7. Electromagnetic Compatibility and Wireless Coexistence

The subject device is identical to the currently marketed Omnipod DASH Insulin Management System (k182630). Safety, Electrical Safety, and EMC testing were conducted on the Omnipod DASH Insulin Management System, consisting of the Pod and PDM, in accordance with IEC 60601-1 for Basic Safety and Essential Performance, IEC 60601-1-2 for Electromagnetic Disturbances, IEC 60601-1-6 for Usability, IEC 60601-1-8 for Alarms, IEC 60601-1-11 for Systems Used in the Home Healthcare Environment.

8. Electrical Safety and Essential Performance

The sponsor demonstrated testing for safety requirements for electrical equipment in compliance with IEC 60601-1, including compliance with the following collateral standards: IEC 60601-1-8, IEC 60601-1-11, IEC 60601-2-24. All tests passed acceptance criteria.

9. Data Logging

The sponsor provided a summary of pump and PDM logging capability which enable the device to record critical events including insulin delivery, pump commands and confirmations, connectivity states, malfunctions, and alarms. These were reviewed and found to be adequate.

10. 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, their plan covered their approach to working with connected device companies regarding contractual approaches, 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.

11. Cybersecurity

Detailed information on cybersecurity of the device was reviewed and found to be acceptable.

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.