June 1, 2018

Insulet Corporation
Matthew King
Director, Regulatory Affairs & Design Quality Assurance
600 Technology Park Drive, Suite 200
Billerica, Massachusetts 01821

Re: K180045
Trade/Device Name: Omnipod DASH™ Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: May 3, 2018
Received: May 4, 2018

Dear Matthew King:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k180045

Device Name
Omnipod DASH Insulin Management System

Indications for Use *(Describe)*
The Omnipod DASH Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display glucose measurements.

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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omnipod®
INSULIN MANAGEMENT SYSTEM

510(K) SUMMARY COMPLYING WITH 21 CFR 807.92

Date Prepared:	January 5, 2018
Submitter Name:	Insulet Corporation
Submitter Address:	600 Technology Park Drive, Suite 200 Billerica, MA 01821
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3004464228
Contact Person:	Matthew King Director of Regulatory Affairs and Design Quality Assurance
Phone:	(978) 600-7427 (office) (603) 459-9755 (mobile)
Fax:	(978) 600-0120
Device Trade / Proprietary Name:	Omnipod DASH™ Insulin Management System
Device Common Name:	Pump, Infusion, Insulin
Regulation Description:	Infusion pump
Regulation Medical Specialty:	General Hospital
Review Panel(s):	General Hospital
Product Code(s):	LZG (Pump, Infusion, Insulin) NDC (Calculator, Drug Dose)
Regulation Numbers:	21 CFR 880.5725 (Infusion Pump)
Submission Type:	Traditional 510(k)
Device Class:	Class II
Model Number (Pod):	BLE-I1-529
Model Number (PDM):	USA1-D001-MG-USA1
Device Predicate:	K162296 Omnipod® Insulin Management System

Device Description:
The Omnipod DASH™ Insulin Management System provides for the management of insulin therapy by patients with diabetes mellitus. It is comprised of two primary components: the disposable insulin infusion pump (Pod), and an associated Bluetooth Low Energy (BLE) enabled remote controller referred to as the Personal Diabetes Manager (PDM). The PDM can communicate with interoperable, compatible BLE enabled blood glucose meters. The PDM incorporates a suggested bolus calculator which aids the user in determining the insulin bolus dosage needed based on carbohydrates ingested, most recent blood glucose reading, programmable correction factor, insulin to carbohydrate ratio, target blood glucose value and Insulin on Board (IoB).

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 PDM is a handheld device that controls the Pod. The user interfaces with the device system through the PDM using a touch screen, similar to a smartphone, where they control basal and bolus delivery and various insulin program settings and calculations. The 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.

Indications for Use:
The Omnipod DASH™ Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Additionally, the Omnipod DASH™ System is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements.

Summary of Technological Characteristics Compared to Predicate Device:
The subject and predicate device are each continuous insulin delivery systems that provide all of the proven benefits of Continuous Subcutaneous Insulin Infusion (CSII) therapy. This allows a user to place up to 200 Units of their U100 insulin into a reservoir within the Pod and have it delivered subcutaneously at set and variable rates, depending upon their own individual program and needs. Both devices utilize a pump (Pod) with a hard needle/soft-cannula assembly for infusion. The soft cannula surrounds the hard needle. The hard needle has a beveled distal end that pierces the skin and drives into the subcutaneous space. The design of the hard needle is such that it drives into the subcutaneous space between 4mm and 7mm on recommended sites

on the anatomy of the user. The hard needle immediately retracts back into the Pod housing, leaving the soft cannula behind in the subcutaneous space, allowing for the infusion of the insulin.

In both, the subject and predicate device, insulin is delivered from the Pod reservoir via the same pumping mechanism, which is driven in accordance with commands from the PDM. Both devices enable wireless communication between the Pod and PDM; the subject device communicates via Bluetooth Low Energy (BLE); the predicate device via proprietary Radio Frequency (RF) communication. In the case of each device, the programs communicated from the PDM to the Pod are carried out by the Pod software and hardware, including basal and bolus delivery of insulin. The PDM of both devices has an insulin dose calculator that the user can access in determining their insulin requirements. The dose calculator is the same in both devices, utilizing blood glucose measurement, insulin on board, insulin to carbohydrate ratios, carbohydrate values, and correction factors to assist in calculating doses. Both the subject and predicate devices are able to automatically display blood glucose measurements from a compatible blood glucose meter (BGM), with the subject device communicating wirelessly with a compatible BGM, while the predicate has a BGM embedded in the PDM hardware.

At a high level, the subject and predicate devices are based on the same technological elements including:

- Intended use and intended users
- Components
    - Pod (used to deliver the insulin)
    - PDM (used to control the Pod)
- Subcutaneous delivery of insulin
- Needle/cannula insertion mechanism
- Pod and PDM communicate wirelessly
- Dose calculation algorithm and parameters
- Fluid path and body contacting components (same design and materials)
- Insulin delivery mechanism
- Pod has same source of power

The following technological differences exist between the subject and predicate devices:

- Use of an Android device as the PDM
- Bluetooth Low Energy communication
- Re-designed User Interface
- Interoperable with BLE compatible BGM

Performance Data and Standards Compliance:

Safety Assurance Case: An assurance case is provided for the Omnipod DASH™ Insulin Management System as recommended in the FDA Guidance "Infusion Pumps Total Product Life Cycle" dated December 2, 2014. The stated goal of the safety assurance case is:

> The Omnipod DASH™ Insulin Management System with dose calculator is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis.

The three high level arguments in the Safety Assurance Case are:

1. The Omnipod DASH™ Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and has been adequately evaluated for risk mitigations arising from identified hazards.
2. The Omnipod DASH™ Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and has been adequately designed to function for the intended use and the intended period of use defined for the device system.
3. The Omnipod DASH™ Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and the design specifications have been adequately verified and validated.

The supporting evidence demonstrates that the following general categories of hazards have been adequately addressed:

- Infusion Delivery Errors:
    - Incorrect set up of the PDM leading to over-infusion, under-infusion or delay in infusion of insulin.
    - Incorrect entry of insulin prescription leading to overdose or underdose (due to error, incorrect key strokes, accidentally pressing wrong key, confusion, or inadvertently tapping keys).
    - User workaround or bypassing of software limits on insulin dose parameters leading to overdose or underdose of insulin.
    - User error in insulin infusion during pump activation due to misunderstanding of pump operation, leading to overdose or underdose of insulin.
    - User error in insulin infusion during pump activation due to inputting incorrect insulin values, leading to overdose or underdose of insulin.

- User activates incorrect Pod, leading to over-infusion or under-infusion of insulin.
- Accidental use of another user's PDM after Pod activation, leading to over-infusion or under-infusion of insulin.
- EMC or EMI interference causing device malfunction, leading to over-infusion or under-infusion of insulin.
- Battery disconnection or component damage resulting in surge caused by dropping of PDM, leading to over-infusion or under-infusion of insulin.
- Electronic component damage caused by shipping of PDM, leading to incorrect signal to the Pod resulting in over-infusion or under-infusion of insulin.
- PDM exposed to water causing a short resulting in incorrect signals to Pod, leading to over-infusion or under-infusion of insulin.
- PDM screen cracks preventing user from adequately programming bolus, leading to over-infusion or under-infusion of insulin.
- User receives incorrect blood glucose readings from a compatible BGM, resulting in over-infusion or under-infusion of insulin.
- User receives over-infusion of insulin due to stuck PDM keys giving a continual bolus delivery signal to the Pod.
- PDM software algorithm error results in errant insulin infusion program on the Pod causing over-infusion or under-infusion of insulin.
- Device is occluded and insulin flow into subcutaneous tissue is restricted, leading to hyperglycemia.
- Flow from Pod is higher than expected during the basal program or a bolus resulting in over-infusion of insulin.
- PDM loses backup power and loses the date and time resulting in a Pod being rendered unusable, leading to an unanticipated delay in insulin infusion and hyperglycemia.
- Pod encounters partial deploy/partial retraction of needle mechanism upon firing into subcutaneous tissue resulting in under-infusion and hyperglycemia.
- Pod encounters partial deploy, failed deploy, or partial retract due to lack of clearance between components of needle mechanism resulting in under-infusion of insulin and hyperglycemia.
- Pod encounters partial deploy or partial retract due to interference of needle mechanism resulting in under-infusion of insulin and hyperglycemia.

- Plunger is changed and fails to operate as intended, leading to a defective Pod, leading to a delay in use which may lead to hyperglycemia.
- Pod software fails prior to or during operation, stopping infusion and resulting in an alarm, which could cause delay in treatment and hyperglycemia.
- Pod does not activate upon command, spring latch does not release drive mechanism, resulting in a failed Pod and hyperglycemia.
- Pod top housing loses structural integrity and all function is lost, resulting in delay in treatment and hyperglycemia.
- Pod has no audible alarm that user can hear resulting in a missed occlusion alarm, which could lead to hyperglycemia.
- Software corruption due to software updates to the device, which may lead to hyperglycemia.
- User activates Pod and the needle does not deploy, leading to hyperglycemia.
- Pod needle does not achieve required depth and angle for adequate infusion, leading to hyperglycemia.
- User miscalculates the amount of carbs they have consumed resulting in a bolus that is too high or too low to account for their insulin requirement, which may lead to hypoglycemia or hyperglycemia.
- The user selects a bolus that is greater than what is needed and experiences hypoglycemia.
- The user does not correct their current BG from their target BG and thus does not calculate their bolus correctly and experiences hyperglycemia.
- The user miscalculates their correction bolus by not taking insulin already present in their body (insulin on board) into account and experiences hypoglycemia.
- The user is not able to calculate a meal bolus and experiences hyperglycemia.
- The user is not able to calculate the insulin on board with a meal bolus and experiences hypoglycemia.
- The user experiences an occlusion at the time of a bolus infusion. When the occlusion clears, the bolus is delivered and the user experiences hypoglycemia (post-occlusion bolus).

- Incorrect therapy or treatment
- Harm resulting from non-secure communication (cybersecurity)
- Biological or chemical contamination
    - Insulin potency impacted by material leaching out of the fluid path materials, leading to chemical contamination, hypoglycemia, or hyperglycemia.
    - Insulin sterility not maintained over the Pod wear period, resulting in infection.
    - Body contacting parts of System cause biocompatibility issues to the user's skin and other bodily tissues, resulting in inconvenience to serious injury.
    - Insulin fill syringe is manufactured with materials that leach into subcutaneous tissue and patient experiences toxic response and is injured.
    - Fluid path of Pod manufactured with materials that leach into subcutaneous tissue and patient experiences toxic response and is injured.
- Traumatic injury
    - User receives electrical shock from PDM
    - User receives electrical shock from Pod

Risk Management: Performed and completed in accordance with ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices. Verification activities, as required by the risk analysis, demonstrate that the predetermined acceptance criteria were met and the device is free of unacceptable risk.

Biocompatibility: 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.

Safety, Electrical Safety, and Electromagnetic Compatibility (EMC): 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.

Software: Software verification and validation testing was conducted and documentation provided in accordance with IEC 62304, FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005. Cybersecurity testing was conducted and documented in accordance with FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" dated October 2, 2014. The software for this medical device system is considered as a "major" level of concern, since a failure or latent flaw in the software could result in serious injury or death to the patient.

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
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 60601-1
Occlusion Detection Testing
Suspend and Resume Testing
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
BGM Functions Testing
Insulin Delivery Verification Testing
Regression Analysis and Testing

Human Factors: Validation of the device system was performed in accordance with FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016 and IEC 62366-1, in which safety critical tasks were identified, had safeguards identified and implemented, then tested for their residual risk. The Omnipod DASH™ System validation demonstrated that the device is validated for its intended use.

Compliance to Standards: The Omnipod DASH™ Insulin Management System has had its design considered in accordance with the Guidance for Industry and FDA Staff: Infusion Pumps Total Product Life Cycle, released December 2, 2014. According, the system complies with the following standards as documented in the applicable test reports provided in this 510(k) submission. Verification and validation reports demonstrate that the Omnipod DASH™ Insulin Management System is validated for its intended use.

- **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)]

Applicable FDA Guidance Documents:
The following FDA Guidance documents were used to demonstrate substantial equivalence of the Omnipod DASH™ Insulin Management System to the predicate device:

- 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

Substantial Equivalence Conclusion:
The Omnipod DASH™ Insulin Management System uses the same technology, indications for use, and modes of operation as the predicate Omnipod® Insulin Management System cleared under K162296. The proposed modifications in the Omnipod DASH™ Insulin Management System results in a device that is substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness. Performance testing of the Omnipod DASH™ Insulin Management System demonstrated that the subject device met all device specifications. Therefore, the subject device is substantially equivalent to the predicate device.