January 8, 2019

Insulet Corporation
Julie Perkins
Director, Regulatory Affairs/Quality Assurance
100 Nagog Park
Acton, Massachusetts 01720

Re: K182630
Trade/Device Name: Omnipod Insulin Management System, Omnipod DASH Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG, NBW, NDC
Dated: December 5, 2018
Received: December 6, 2018

Dear Julie Perkins:

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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for 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)*
K182630

Device Name
Omnipod Insulin Management System, Omnipod DASH Insulin Management System

Indications for Use *(Describe)*

Omnipod Insulin Management System

The Omnipod® 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 and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis or screening for diabetes. The PDM glucose meter is intended for single patient use and should not be shared.

Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Omnipod DASH Insulin Management System

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.1 510(K) SUMMARY

510(k) Summary Complying with 21 CFR 807.92

Date prepared:	January 8th, 2019
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park Acton, MA 01720
Contact Person:	Julie Perkins Director of Regulatory Affairs and Quality Assurance
Phone:	(978) 600-7951(office)
Fax:	(978) 600-0120
Device Trade / Proprietary Name:	Omnipod® Insulin Management System Omnipod DASH™ Insulin Management System
Device Common Name:	Pump, Infusion, Insulin
Regulation Description:	Infusion pump
Regulation Medical Specialty:	General Hospital
Review Panel:	General Hospital
Product Code:	LZG (Insulin Infusion Pump) NBW (System, Test, Blood Glucose, Over the Counter) NDC (Calculator, Drug Dose)
Submission Type:	Traditional 510(k)
Regulation Number:	880.5725
Device Class:	Class II

Device predicate:

K162296 Omnipod® Insulin Management System
K180045 Omnipod DASH™ Insulin Management System

Purpose of Submission:
Modification to K162296 Omnipod® Insulin Management System and K180045 Omnipod DASH™ Insulin Management System to address design and labeling changes.

Device Description:

The subject devices provide for the management of insulin therapy and blood glucose monitoring by patients with diabetes mellitus. They are each comprised of two primary components: the disposable insulin infusion pump (Pod) and an associated wireless remote controller referred to as the Personal Diabetes Manager (PDM). The PDMs incorporate 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, 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 Omnipod Insulin Management System PDM has an integrated blood glucose meter and communicates with the Pod using wirelessly using secure, low power, bi-directional radio frequency (RF) communications at 433.92MHz. The Omnipod DASH Insulin Management System PDM does not have an integrated blood glucose meter, but is interoperable with a compatible blood glucose meter to receive and display glucose measurements. The Omnipod DASH PDM communicates to the Pod and a compatible blood glucose meter using Bluetooth Low Energy.

Both systems are for prescription use only.

Indications for Use:

Omnipod Insulin Management System
The Omnipod® 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 and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis or screening for diabetes. The PDM glucose meter is intended for single patient use and should not be shared.

Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Omnipod DASH Insulin Management System
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.

The subject devices have the same intended use and indications for use as their predicates.

Summary of Technological Characteristics Compared to Predicate Device:

The energy source, principles of operation, and configuration of the Omnipod® Insulin Management System and Omnipod DASH Insulin Management System are not changed from those cleared in K162296 and K180045, respectively. The same modifications are being proposed to both systems as compared to the predicates include:

Hardware: Addition of two holes at the end of the cannula for a total of three ports for insulin diffusion. As part of this design change, the cannula depth of insertion and the depth of infusion specifications have been modified. There have been no changes to the material of the cannula.

Labeling: Addition of Admelog U100 as an insulin that has been tested for use with the Omnipod Systems.

There have been no changes to the device materials, software, sterilization method, or packaging of the systems that are subject of this 510(k).

Performance Data and Standards Compliance:

The following performance testing data were provided in support of the substantial equivalence determination.

- **Drug Stability and Compatibility;** In-use stability and leachables testing was conducted with Admelog U100 insulin to verify and validate that the systems do not adversely affect the insulin.

- **Soft Cannula Studies;** testing was conducted to verify that the modified soft cannula design met the insertion depth and new insulin infusion depth specifications.

- **Real-world data analysis;** An analysis of OUS post-market data gathered from devices with and without the modified cross-drilled soft cannula was conducted to compare the performance of the new design to the predicate devices. The analysis concluded that the modification did not raise any new questions of safety and effectiveness as compared to the predicate devices.

- **Sterilization;** A sterilization product adoption was conducted in accordance with AAMI TIR28:2016 and bioburden testing was conducted in accordance with ISO 11737-1 for the modified soft cannula design.

- **Safety Assurance Case;** An assurance case for the design modifications was provided for each system as recommended in the FDA Guidance: Infusion Pumps Total Product Life Cycle.

  The stated goal of the Omnipod Insulin Management System safety assurance case is:

  > The Omnipod Insulin Management System with blood glucose monitor and 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 stated goal of the Omnipod DASH Insulin Management System 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.

Additions to the safety assurance cases from the predicate devices' cases included modified soft cannula design and use of the devices with Admelog.

- **Risk Management;** was completed in accordance with ISO 14971:2007- Medical Devices- Application of Risk Management to Medical Devices. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the devices are safe for use.

The Omnipod Insulin Management System and the Omnipod DASH Insulin Management System comply with the following standards as documented in the predicate devices (K162296 and K180045) and in the applicable test reports provided in this 510(k) submission.

- ISO 10993-1 (2009)- 4th Edition Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process
- ISO 14971 Second Edition 2007-03-01 Medical Devices- Application of Risk Management to Medical Devices
- ISO 11737-1 (2018) Sterilization of health care products- Microbiological methods- Part 1: Determination of the population of microorganisms on products
- 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 TIR28 (2016) Product adoption and process equivalence for ethylene oxide sterilization

Substantial Equivalence Conclusion:

The Omnipod® Insulin Management System and Omnipod® DASH Insulin Management System use similar technology, modes of operation, and indications for use as the predicate devices cleared in K162296 and K180045, respectively. The comparison of intended use and performance data demonstrate that the changes to the subject devices are substantially equivalent to the predicate devices. Therefore, the subject devices are substantially equivalent to the predicate devices.