September 20, 2019

Insulet Corporation
Julie Perkins
Sr. Director, Quality Assurance and Regulatory Affairs
100 Nagog Park
Acton, MA 01720

Re: K191679
Trade/Device Name: Omnipod DASH Insulin Management System with interoperable technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG
Dated: June 21, 2019
Received: June 24, 2019

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 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.
Acting 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

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)*
K191679

Device Name
Omnipod DASH Insulin Management System with interoperable technology

Indications for Use *(Describe)*
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.

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.

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5.0 510(K) SUMMARY

Date Prepared:	September 11, 2019
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park, Acton, MA, 01720
FDA Establishment Owner/Operator Number: **FDA Establishment Registration Number:**	9056196 3014585508
Contact Person: **Phone:** **Fax:**	Julie Perkins Sr. Director, Quality Assurance and Regulatory Affairs 978-600-7951 (office) 987-600-0120
Device Trade / Proprietary Name:	Omnipod DASH™ Insulin Management System with interoperable technology
Device Common Name:	Alternate controller enabled infusion pump
Regulation Description:	Infusion pump
Regulation Medical Specialty:	Hematology
Review Panel(s):	Clinical Chemistry
Product Code(s):	QFG
Regulation Numbers:	21 CFR 880.5730
Submission Type:	Traditional 510(k)
Device Class: **Model Number (Pod):** **Model Number (PDM):**	Class II BLE-I1-529 USA1-D001-MG-USA1
Device Predicate:	DEN180058, t:slim X2 insulin pump with interoperable technology

Purpose of Submission:
Modification to legally marketed device to expand the indications for use.

Device Description:
The Omnipod DASH™ Insulin Management System with interoperable technology 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. The Omnipod DASH System with interoperable technology is provided with the DASH Personal Diabetes Manager (PDM), but future alternate controllers may be established. The DASH 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 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 Delivery (AID) systems. In this design, a controller may contain an algorithm and connect to an iCGM system. In such an integrated system, the AID controller would be responsible for coordinating the interoperable devices (Omnipod DASH and iCGM) in order to automate delivery. It would read the Pod for insulin delivery status, read the iCGM for the sensor value, compute an automated delivery amount 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.

12.1 **Indications for Use:**
The Omnipod DASH Insulin Management System (the Pump) with interoperable technology is intended for the 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.

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 and predicate device are both insulin infusion pumps composed of a software-controlled, programmable pump capable of both basal and bolus delivery of insulin. The technological characteristics differ from the predicate, however the system is the same as the currently marketed Omnipod DASH system (K182630). The differences between predicate and subject device do not raise any questions about safety and effectiveness, therefore, the Omnipod DASH System with interoperable technology is substantially equivalent to its predicate.

Performance Data and Compliance with Special Controls

Special Control	Omnipod DASH with interoperable technology (Subject Device)
Evidence demonstrating that device infusion delivery accuracy conforms to defined user needs and intended uses and is validated to support safe use under actual use conditions. i. Design input requirements must include delivery accuracy specifications under reasonably foreseeable use conditions, including ambient temperature changes, pressure changes (e.g., headheight, backpressure, atmospheric), and, as appropriate, different drug fluidic properties. ii. Test results must demonstrate that the device meets the design input requirements for delivery accuracy under use conditions for the programmable range of delivery rates and volumes. Testing shall be conducted with a statistically valid number of devices to account for variation between devices.	All the performance testing provided in K182630 and K180045 are applicable to the subject device. Further characterization has been conducted and submitted in this 510(k).
Validation testing results demonstrating the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (e.g., occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes. Hazard detection must be	The subject device is identical to the DASH system in K182630 (initially cleared in K180045). All testing, except delivery accuracy, was completed to demonstrate the ability of Omnipod DASH with interoperable technology to detect relevant hazards associated with insulin delivery and was provided in K182630 and

appropriate for the intended use of the device and testing must validate appropriate performance under the conditions of use for the device.	K180045. Delivery accuracy was conducted for this submission. Traceability of hazards to risk controls and verification evidence is included in the System Hazard Analysis provided in this submission.
Validation testing results demonstrating compatibility with drugs which may be used with the pump based on its labeling. Testing must include assessment of drug stability under reasonably foreseeable use conditions which may affect drug stability (e.g., temperature, light exposure, or other factors as needed).	The subject device is identical to the DASH system in K182630 (initially cleared in K180045). All validation testing to demonstrate the Omnipod DASH Insulin Management System with interoperable technology is compatible with insulin was provided in K180045 and K182630.
The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible. This shall include chemical and particulate characterization on the final, finished, fluid contacting device components demonstrating that risk of harm from device-related residues is reasonably low.	The subject device is identical to the DASH system in K182630 (initially cleared in K180045). The biocompatibility of parts that directly contact the patient (adhesive pad) was demonstrated with cytotoxicity, sensitization, and skin irritation studies- with the exception of chronic toxicity and carcinogenicity as it was determined that the Omnipod DASH with interoperable technology is not a risk for these. All results were passing. The biocompatibility of parts that indirectly contact the patient, those that are in the fluid path, was demonstrated with cytotoxicity, sensitization, intracutaneous reactivity, acute system toxicity, material mediated pyrogenicity, subacute/subchronic toxicity, genotoxicity, implantation, and hemocompatibility. All results were passing.
Evidence verifying and validating that the device is reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.	The subject device is identical to the DASH system in K182630 (initially cleared in K180045). No additional shelf life testing was completed for Omnipod DASH with interoperable technology.
The device must be designed and tested for electrical safety, electromagnetic compatibility, and radio frequency wireless safety and	The subject device is identical to the DASH system in K182630 (initially cleared in K180045). No additional electrical safety and

availability consistent with patient safety requirements in the intended use environment.	electromagnetic compatibility testing was completed for Omnipod DASH with interoperable technology.
For any device that is capable of delivering more than one drug, the risk of cross-channeling drugs must be adequately mitigated.	Omnipod DASH is only intended for U-100 insulin delivery.
For any devices intended for multiple patient use, testing must demonstrate validation of reprocessing procedures and include verification that the device meets all functional and performance requirements after reprocessing.	Omnipod DASH with interoperable technology is only intended for single-patient use. The DASH Pod is a single-use disposable component which provided insulin delivery for 3 days. The PDM is a non-sterile single-use patient component.
The device shall include validated interface specifications for digitally connected devices. These interface specifications shall, at a minimum, provide for the following: a. Secure authentication (pairing) to external devices. b. Secure, accurate, and reliable means of data transmission between the pump and connected devices. c. Sharing of necessary state information between the pump and any digitally connected alternate controllers (e.g., battery level, reservoir level, pump status, error conditions). d. Ensuring that the pump continues to operate safely when data is received in a manner outside the bounds of the parameters specified. e. A detailed process and procedure for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.	The interface between the Omnipod DASH controller (PDM) and pump (DASH Pod has been specified and validated. Insulet has a detailed process established for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.
The device design must ensure that a record of critical events is stored and accessible for an adequate period to allow for auditing of communications between digitally connected devices, and to facilitate the sharing of pertinent	The design intent of the Omnipod DASH with interoperable technology is for all insulin delivery commands that the controller (PDM)

information with the responsible parties for those connected devices. Critical events to be stored by the system must, at a minimum, include: a. A record of all drug delivery b. Commands issued to the pump and pump confirmations c. Device malfunctions d. Alarms and alerts and associated acknowledgements e. Connectivity events (e.g., establishment or loss of communications)	sends to the pump (DASH Pod) be logged in the PDM's memory. a. The execution of insulin delivery commands is stored in the DASH Pod's memory as a record of basal and bolus pulses delivered. b. In addition to storing a record of insulin delivery commands sent, the PDM also stores a record of the execution of the commands once it receives confirmation from the DASH Pod that the command was executed. c. The combination of the DASH Pod log and PDM log allows Insulet to audit failures of the system and determine root causes. This log includes all of the requirements outlined in the special controls. d. The PDM stores 90 days' worth of a records of all alarms, alerts and acknowledgements. e. The PDM stores a short duration (approximately 3 days, depending on activity) of records of communication connectivity events. Insulet's intention with any partner for an integrated system incorporating Omnipod DASH with interoperable technology is to ensure these logging requirements are met and verified for an external controller, in order to ensure full capability to audit for failures of the integrated system. Additionally, as with the current PDM, an external controller will have the ability to query the DASH Pod data.
Design verification and validation must include results obtained through a human factors study that demonstrates that an intended user can safely use the device for its intended use.	The Omnipod DASH Insulin Management System with interoperable technology (subject device) has an expanded indication from the currently marketed version (cleared via K182630). This expanded indication as an alternate controller enabled (ACE) pump did not require any design or manufacturing modifications to the currently cleared Omnipod DASH system, therefore, all the performance

	testing provided in K182630 and K180045 are applicable to the subject device.
Device labeling must include the following: a. A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate. b. A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters. c. A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: number of bolus doses with volume that is 250% of the commanded amount. d. A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warm-up period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on	The Omnipod DASH User Guide has been updated to contain the information from the special controls.

the drug delivered) may be provided as follows, as applicable: i. The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point. e. A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps. f. For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device. g. For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.	

Compliance to Standards: The modified indications for use for the does not require any additional testing in accordance with recognized standards. Updated risk assessments for modified intended use was done in accordance with ISO 14971 *Medical Devices – Application of Risk Management to Medical Devices*, second edition (2007-03-01).

Substantial Equivalence Conclusion:

The Omnipod DASH™ Insulin Management System with interoperable technology has the indications for use and modes of operation as the predicate t:slim X2 insulin pump with interoperable technology (DEN180058). The evidence provided in this 510(k) demonstrates the Omnipod DASH™ Insulin Management System with interoperable technology to be a device that is as safe and effective as the predicate device and does not raise new questions of safety and effectiveness. Performance testing of the Omnipod DASH™ Insulin Management System with interoperable technology demonstrated that the subject device met all device specifications. Therefore, the subject device is substantially equivalent to the predicate device.