August 13, 2021

Insulet Corporation
Dennis Shay
Regulatory Affairs Manager
100 Nagog Park
Acton, MA 01720

Re: K211575
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: May 20, 2021
Received: May 21, 2021

Dear Dennis Shay:

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.
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211575

Device Name
Omnipod Insulin Management System

Indications for Use *(Describe)*
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 of 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211575

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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Insulet Corporation

5.0 510(K) SUMMARY

Date prepared:	11 August 2021
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park Acton, MA 01720
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3014585508
Contact Information:	Dennis Shay, PhD Regulatory Affairs Manager (978) 846-1247 (office) (978) 600-0120 (fax)
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:	Clinical Chemistry
Review Panel:	Clinical Chemistry
Product Code:	LZG (Infusion Pump) Subsequent: 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:	K192659 Omnipod Insulin Management System and Omnipod DASH Insulin Management System

5.1 Purpose of Submission

Modification to legally marketed devices to add Lyumjev U100 to the labeling as an insulin that is compatible with the systems.

5.2 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.

5.2.1 Indications for Use

5.2.1.1 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.

5.2.1.2 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.

5.3 Summary of Technological Characteristics Compared to Predicate Device

The subject devices are identical to the predicate devices cleared in K192659. There have been no modifications to the materials, design, sterilization method, software, or manufacturing processes. The only difference is adding Lyumjev™ U100 insulin to the labeling as an insulin that has been tested and found safe to use with both systems.

5.4 Performance Data

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

5.4.1 Drug Stability and Compatibility

In-use stability and leachables testing was conducted with Lyumjev U100 insulin to verify and validate that the systems do not adversely affect the insulin.

5.5 Safety Assurance Case

A safety assurance case for the labeling change to add Lyumjev 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 include the use of the device with Lyumjev U100.

5.5.1 Risk Management

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.

5.5.2 Standards Compliance

The Omnipod Insulin Management System and the Omnipod DASH Insulin Management System comply with the following standards as documented in the predicate devices (K192659) and in the applicable test reports provided in this 510(k) submission.

- **ISO 10993-1 (2018)-** 4th Edition Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process
- **ISO 14971 Second Edition (2007)** Medical Devices- Application of Risk Management to Medical Devices

5.6 Summary of Substantial Equivalence to the Predicate

The devices described in this 510(k) are equivalent to those cleared in K192659. The equivalence is based upon the fact that the subject and predicate devices have the same principals of operation, technological characteristics and, indications for use. The only difference between the subject and predicate devices is the addition of Lyumjev U100 to the labeling as an insulin that is compatible with the systems. The following tables below illustrate the equivalence of the subject devices to their predicate.

Table 5-1: Substantial Equivalence Comparison Table for the Omnipod Insulin Management System.

Element Of Comparison	Subject Device: Omnipod Insulin Management System	Predicate Device: Omnipod Insulin Management System (K192659)	Discussion
Intended Use	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). The glucose measurements should not be used for the diagnosis of 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.	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). The glucose measurements should not be used for the diagnosis of 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.	Same

Specific Drug/Biologic Use	U-100 Insulin. System has been tested with NovoLog, Humalog, Apidra, Admelog, Fiasp, and Lyumjev	U-100 Insulin. System has been tested with NovoLog, Humalog, Apidra, Admelog, and Fiasp	Lyumjev U100 is a Fast-acting Insulin Lispro-aabc. Performance testing demonstrates that the use of Lyumjev has no effect on safety
Prescription Status	Prescription Device	Prescription Device	Same
Components and Accessories	Pump (Pod), hand-held controller (PDM) with integrated Freestyle blood glucose meter. Accessories include batteries, test strips, lancets, control solution, prep pads and carry pouch.	Pump (Pod), hand-held controller (PDM) with integrated Freestyle blood glucose meter. Accessories include batteries, test strips, lancets, control solution, prep pads and carry pouch.	Same
Infusion pump	Pod, fill syringe, fill needle	Pod, fill syringe, fill needle	Same
Pumping Mechanism	Step Drive Mechanism is activated by microprocessor; turns leadscrew; presses on syringe style reservoir.	Step Drive Mechanism is activated by microprocessor; turns leadscrew; presses on syringe style reservoir.	Same
Administrative Sets And	Integrated reservoir and patient activated cannula insertion system.	Integrated reservoir and patient activated cannula insertion system.	Same
Non-Fluid Pathway Materials	Pod Housing: Polycarbonate Adhesive: Biocompatible Medical Grade Acrylic Adhesive with a Non-woven Polyester Backing	Pod Housing: Polycarbonate Adhesive: Biocompatible Medical Grade Acrylic Adhesive with a Non-woven Polyester Backing	Same

Fluid Pathway Materials	Perfluorocopolymer (FEP) Silicone Lubricants Stainless Steel Silicone Rubber Polypropylene Polyvinylchloride (PVC) Cyclic Olefin Copolymer Polypropylene & EPDM Rubber (non-latex) Polyisoprene	Perfluorocopolymer (FEP) Silicone Lubricants Stainless Steel Silicone Rubber Polypropylene Polyvinylchloride (PVC) Cyclic Olefin Copolymer Polypropylene & EPDM Rubber (non-latex) Polyisoprene	Same
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. 7 Basal Profiles	Basal: 0.05 -30 units/hour in 0.05 unit increments. Bolus: 0.05 - 30 units in 0.05 unit increments. 7 Basal Profiles	Same
Maximum Bolus Flow Rate	1.5 units per minute	1.5 units per minute	Same
Delivery Accuracy	Basal: ± 5% at rates ≥ 0.05 U/hr Bolus: ± 5% for all set values ≥ 1.0 unit, ± 0.05 unit for set values < 1.0 unit	Basal: ± 5% at rates ≥ 0.05 U/hr Bolus: ± 5% for all set values ≥ 1.0 unit, ± 0.05 unit for set values < 1.0 unit	Same
Sterilization	EO SAL 10^{-6}	EO SAL 10^{-6}	Same
BG Assay Method	Coulometric Electrochemical Sensor	Coulometric Electrochemical Sensor	Same
Calibration Equivalent	Plasma Equivalent	Plasma Equivalent	Same
Hematocrit	15% to 65%	15% to 65%	Same
Sample	Whole Blood, Capillary	Whole Blood, Capillary	Same

Sample Size	300 nanoliters (1/3 or .3 microliter)	300 nanoliters (1/3 or .3 microliter)	Same
Result Range	20-500 mg/dL	20-500 mg/dL	Same
Test Time	Average of 7 seconds	Average of 7 seconds	Same

Table 5-*2*: Substantial Equivalence Comparison Table for the Omnipod DASH Insulin Management System

Element Of Comparison	**<u>Subject Device:</u> Omnipod DASH Insulin Management System**	**<u>Predicate Device:</u> Omnipod DASH Insulin Management System (K192659)**	**Discussion**
Intended Use	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.	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.	Same
Specific Drug/Biologic Use	U-100 Insulin. System has been tested with NovoLog, Humalog, Apidra, Admelog, Fiasp, and Lyumjev	U-100 Insulin. System has been tested with NovoLog, Humalog, Apidra, Admelog, and Fiasp	Lyumjev U100 is a Fast-acting Insulin Lispro-aabc. Performance testing demonstrates that the use of Lyumjev has no effect on safety and effectiveness.

Prescription Status	Prescription Device	Prescription Device	Same
Components and Accessories	Pump (Pod), hand-held controller (PDM), carry case, BLE compatible blood glucose meter.	Pump (Pod), hand-held controller (PDM), carry case, BLE compatible blood glucose meter.	Same
Pump/PDM Communication	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same
Infusion pump	Pod, fill syringe, fill needle	Pod, fill syringe, fill needle	Same
Pumping Mechanism	Step Drive Mechanism is activated by microprocessor; turns leadscrew; presses on syringe style reservoir.	Step Drive Mechanism is activated by microprocessor; turns leadscrew; presses on syringe style reservoir.	Same
Administrative Sets and Reservoir	Integrated reservoir and patient activated cannula insertion system.	Integrated reservoir and patient activated cannula insertion system.	Same
Flow Rates and Profiles	Basal: 0.05 - 30 units/hourin 0.05 unit increments. Bolus: 0.05 - 30 units in 0.05 unit increments. 12 Basal Profiles	Basal: 0.05 - 30 units/hourin 0.05unit increments. Bolus: 0.05 - 30 units in 0.05 unit increments. 12 Basal Profiles	Same
Maximum Bolus Flow Rate	1.5 units per minute	1.5 units per minute	Same
Delivery Accuracy	Basal: ± 5% at rates ≥ 0.05 U/hr Bolus: ± 5% for all set values ≥ 1.0 unit, ± 0.05 unit for set values < 1.0 unit	Basal: ± 5% at rates ≥ 0.05 U/hr Bolus: ± 5% for all set values ≥ 1.0 unit, ± 0.05 unit for set values < 1.0 unit	Same
Power Requirements	Disposable Batteries - Pod Rechargeable Battery - PDM	Disposable Batteries - Pod Rechargeable Battery - PDM	Same
Non-Fluid Pathway Materials	Pod Housing: Polycarbonate Adhesive: Biocompatible Medical Grade Acrylic Adhesive with a Non-woven Polyester Backing	Pod Housing: Polycarbonate Adhesive: Biocompatible Medical Grade Acrylic Adhesive with a Non-woven Polyester Backing	Same
Fluid Pathway Materials	Perfluorocopolymer (FEP) Silicone Lubricants Stainless Steel	Perfluorocopolymer (FEP) Silicone Lubricants Stainless Steel	Same

	Silicone Rubber Polypropylene Polyvinylchloride (PVC) Cyclic Olefin Copolymer Polypropylene & EPDM Rubber (non-latex) Polyisoprene	Silicone Rubber Polypropylene Polyvinylchloride (PVC) Cyclic Olefin Copolymer Polypropylene & EPDM Rubber (non-latex) Polyisoprene	
Alarm Functions	Hazard Alarms • Empty Reservoir • Occlusion • Pump Error • System Error • Auto Off • Low Battery Warning Pod expiration (80 hours)	Hazard Alarms • Empty Reservoir • Occlusion • Pump Error • System Error • Stuck Key • Auto Off • Low Battery Warning Pod expiration (80 hours)	Same
Operating Relative Humidity	20 to 85%	20 to 85%	Same
Operating Temperature	41°F to 104°F (5°C to 40°C)	41°F to 104°F (5°C to 40°C)	Same
Measurement Units (blood glucose reading)	mg/dL	mg/dL	Same
Memory	90 days-worth of information on average Insulin delivery Blood glucose results Carbohydrate intake Alarms	90 days-worth of information on average Insulin delivery Blood glucose results Carbohydrate intake Alarms	Same
Sterilization	EO SAL 10-6	EO SAL 10-6	Same
Shelf life	18 months	18 months	Same

5.7 Substantial Equivalence Conclusion

The subject Omnipod Insulin Management System and Omnipod DASH Insulin Management System use the same technology, modes of operation, and indications for use as the devices cleared in K192659. The only difference between the subject and predicate devices is the addition of Lyumjev U100 to the labeling as an insulin that is compatible with the systems. Insulin stability and compatibility testing demonstrate that the subject devices are as safe, as effective, and perform as well or better than the predicate devices. Therefore, the subject devices are substantially equivalent to the predicate devices.