Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information

A 510(k) Number

K211575

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod Insulin Management System and Omnipod DASH Insulin Management System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZG	Class II	21 CFR 880.5725 - Infusion Pump	CH - Clinical Chemistry
NBW	Class II	21 CFR 862.1345 – Glucose Test System	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 – Predictive pulmonary-function value calculator	CH - Clinical Chemistry

E Purpose for Submission

This submission seeks to expand the device labeling of the Insulet Omnipod and Omnipod DASH Insulin Management Systems (K192659) to include an additional insulin, Lyumjev U-100 (Eli Lilly).

II Intended Use/Indications for Use

A Intended Use(s)

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statements

Both devices are for prescription use only.

The Omnipod® Systems are 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® (insulin aspart), Fiasp® (insulin aspart), Humalog® (insulin lispro), Lyumjev™ (insulin lispro-aabc), Apidra® (insulin glulisine) or Admelog® (insulin lispro). Novolog, Fiasp, Humalog, Lyumjev, and Admelog are compatible with the Omnipod Systems for use up to 72 hours (3 days). Apidra is compatible with the Omnipod Systems for use up to 48 hours (2 days). If you have questions about using other insulins, contact your healthcare provider. Fiasp and Lyumjev have a faster initial absorption than other rapid-acting U-100 insulins; always consult with your healthcare provider and refer to the insulin labeling prior to use.

Omnipod Insulin Management System

Insulin pump therapy is not recommended for people who are:

- Unable to perform at least four (4) blood glucose tests per day
- Unable to maintain contact with their healthcare provider
- Unable to use the System according to instructions

Do not use the built-in blood glucose meter for:

- Testing on neonates
- Testing arterial blood
- Diagnosing of or screening for diabetes mellitus
- Patients who are critically ill, dehydrated, or in diabetic ketoacidosis (DKA)

Omnipod DASH® Insulin Management System

Insulin pump therapy is not recommended for people who are:

- Unable to monitor blood glucose levels as recommended by their healthcare provider
- Unable to maintain contact with their healthcare provider
- Unable to use the Omnipod DASH® System according to the instructions

III 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 wirelessly using secure, low power, bi-directional radio frequency (RF) communications. 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.

IV Substantial Equivalence Information

A Predicate Device Name(s)

Omnipod Insulin Management System and Omnipod DASH Insulin Management System

B Predicate 510(k) Number(s)

K192659

C Comparison with Predicate(s)

Device & Predicate Device(s):	K211575	K192659
Device trade name	**Omnipod Insulin Management System and Omnipod DASH Insulin Management System**	**Omnipod Insulin Management System and Omnipod DASH Insulin Management System**
General Device Characteristic Similarities		
Intended Use	Intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.	Same
General Device Characteristic Differences		
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.

V Standards/Guidance Documents Referenced

- ISO 14971 Second Edition: 2007, Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1 Fifth Edition: 2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

VI Performance Characteristics

In vitro stability and leachables testing were conducted with Lyumjev U-100 insulin to verify that the pumps and the insulin are compatible. The stability of the insulin product was evaluated under stressed, worst-case conditions. The studies observed acceptable results of degradation products and leachables, and support the compatibility of this insulin product with these pumps.

A comprehensive hazard analysis for this device was prepared in accordance with ISO 14971 Second Edition: 2007, Medical Devices – Application of Risk Management to Medical Devices. The risk management process included elements of risk analysis, risk evaluation, risk control, and production and post-production information. A safety assurance case was also prepared in accordance with *FDA Guidance for Industry and FDA Staff: Infusion Pumps Total Product Lifecycle, December 2, 2014*.

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.