



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K223372

B Applicant

Insulet Corporation

C Proprietary and Established Names

Omnipod GO Insulin Delivery Device

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZG	Class II	21 CFR 880.5725 - Infusion Pump	CH - Clinical Chemistry

E Purpose for Submission:

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Omnipod GO Insulin Delivery Device is intended for the subcutaneous infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with type 2 diabetes.

C Special Conditions for Use Statement(s):

This device is for prescription use only.

Insulin pump therapy is NOT recommended for people who:

- are unable to monitor glucose as recommended by their healthcare provider.

- are unable to maintain contact with their healthcare provider.
- are unable to use the Omnipod GO Pod according to instructions.
- do NOT have adequate hearing and/or vision to allow recognition of Pod lights and sounds that signify alerts and alarms.

The Pod must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, and diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the Pod.

The device is designed to use rapid-acting U-100 insulin. The Omnipod GO Pod is compatible with the following U-100 insulins: NovoLog, Fiasp, Humalog, Admelog, and Lyumjev.

III Device Description

The subject device is intended for the subcutaneous infusion of insulin at a preset basal rate (i.e. for a fixed volume in one 24-hour time period) for 3 days (72 hours) in adults with type 2 diabetes. The subject device will have seven different models: 10, 15, 20, 25, 30, 35, and 40 units per day, with each model delivering insulin at a fixed rate over the 72-hour use life of the device. The subject device does not offer the ability to deliver a bolus.

The subject device will be entirely self-contained in an on-body pod that is single-use, sterile, and disposable. It is designed to be attached to the body via an adhesive pad that is heat-staked to the bottom of the pod. The adhesive backing keeps the pod securely in place for up to 3 days (72 hours). The sterilized package of the subject device includes the Omnipod GO pod, a fill syringe, and a fill needle.

The subject device will operate without a controller device such as a Personal Diabetes Manager (PDM), and it will automatically activate when the user fills the reservoir with insulin using the included fill needle and fill syringe. The user has three minutes to apply the pod before the needle and cannula automatically deploy. The device will provide users with visual and audible notifications related to pod set up/insulin fill, activation of basal rate, expiration, and hazardous or error scenarios resulting in deactivation.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Valeritas V-Go Insulin Delivery Device

B Predicate 510(k) Number(s):

K103825

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K223372</u>	<u>K103825</u>
Device Trade Name	Omnipod GO Insulin Delivery Device	Valeritas V-Go Insulin Delivery Device
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the continuous subcutaneous infusion of insulin at a preset basal rate in adults requiring insulin.	Same
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 Insulin. System has been tested with NovoLog, Fiasp, Humalog, Admelog, and Lyumjev.	U-100 Insulin. System has been tested with NovoLog and Humalog.
Insulin Delivery Modes	Basal only	Both basal and bolus
Preset Basal Rates	10, 15, 20, 25, 30, 35, and 40 U/day	20, 30, and 40 U/day
Duration of Use	Up to 72 hours	Up to 24 hours

V Standards/Guidance Documents Referenced:

- ISO 10993-1 2018/Cor.1: 2010, 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 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-6: 2016, Biological Evaluation of Medical Devices - Part 6: Test for Local Effects After Implantation
- ISO 10993-7 2008/Cor 1: 2009, 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: 2017, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 10993-12: 2021, Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials
- ISO 10993-17: 2002, Biological Evaluation of Medical Devices - Part 17: Methods for the establishment of allowable limits for leachable substances
- ISO 10993-18: 2020, Biological Evaluation of Medical Devices - Part 18: Chemical characterization of materials
- ISO 11135 2014+A1: 2018, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1: 2018, Sterilization of health care products - microbiological methods - part 1: Determination of a population of microorganisms on product
- ISO 11607-1: 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019, Packaging for Terminally Sterilized Medical Devices - Part 2: Validation requirements for forming, sealing and assembly processes
- IEC 60601-1-2 Ed. 4.0: 2014, Medical Electrical Equipment- Part 1-2: Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- ISTA 3A: 2018, Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- ASTM F1980-16: 2016, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-16: 2016, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M- 15: 2015, Standard Test method for Peel Strength of Flexible Barrier Materials
- ASTM F2096-11: 2019, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressure (Bubble Test)
- ASTM F1929-15: 2015, Standard Test Method for Detecting Seal Leaks in Medical Packaging by Dye Penetration
- F1886/F1886M-16: 2016, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM D903-98: 2017, Standard Test method for Peel of Stripping Strength of Adhesive Bonds
- IEC 60601-1-6 Ed. 3.1: 2013, Medical Electrical Equipment - Part 1-6: Collateral standard: Usability
- IEC 62366-1 Ed. 1: 2015, Medical Devices – Part 1: Application of usability engineering to medical devices

- ISO 15223-1 Ed. 3: 2016, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ISO 14971 Ed. 2: 2019, Medical Devices - Application of Risk Management to Medical Devices
- IEC 60601-1 Ed. 3.1: 2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI ES60601-1: 2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-8 Ed. 2.1: 2012, Medical Electrical Equipment - Part 1-8: Collateral Standard: Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
- IEC 60601-1-11 Ed. 2.0: 2015, Medical Electrical Equipment - Part 1-11: Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- ISO 23908: 2011, Sharps injury protection – Requirements and test methods – Sharps protection features for single- use hypodermic needles, introducers for catheters and needles used for blood sampling
- IEC 62304 Ed. 1.1: 2015, Medical Devices Software - (Software life cycle processes)

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy, 12 Omnipod GO pumps were tested by delivering at low, medium, and high basal rates (10, 25, and 40 U/day). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess basal delivery accuracy. The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warmup period. For each time period, the tables show the volume of insulin requested (expected delivery volume), the volume that was delivered as measured by the scale, and the minimum and maximum delivery errors as a percentage of the expected delivery volume.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 10 U/day (low) basal rate setting

10 U/day Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	0.42 U	2.50 U	5.00 U
Median amount delivered [min, max]	0.42 U [0.14, 0.64]	2.53 U [1.72, 3.09]	5.05 U [3.83, 5.18]
[min, max] Error %	[-67%, 55%]	[-31%, 24%]	[-23%, 3.6%]

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 25 U/day (medium) basal rate setting

25 U/day Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	1.04 U	6.25 U	12.50 U
Median amount delivered [min, max]	1.07 U [0.46, 1.54]	6.34 U [5.09, 6.88]	12.59 U [11.31, 13.39]
[min, max] Error %	[-56%, 47%]	[-18%, 10%]	[-9.5%, 7.1%]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 40 U/day (high) basal rate setting

40 U/day Basal Duration	1 hour	6 hours	12 hours
Total expected delivery volume	1.67 U	10.00 U	20.00 U
Median amount delivered [min, max]	1.73 U [0.99, 2.28]	10.09 U [9.09, 10.37]	20.19 U [19.13, 20.47]
[min, max] Error %	[-41%, 37%]	[-9.1%, 3.7%]	[-4.3%, 2.4%]

2. Occlusion detection

An occlusion hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. A total of 21 pods were tested for the time to occlusion alarm at the applicable basal rates (10, 15, 20, 25, 30, 35, and 40 U/day) by introducing occlusion to the pods, recording the time for occlusion, and parsing all alarm codes related to occlusion to record occlusion alarm time. The time to occlusion alarm is the difference between the time of occlusion and the time of occlusion alarm.

The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the pod's cannula becomes blocked while using a 25 U/day pod, up to 5.5 hours may pass before the pod sounds a hazard alarm.

Table 4: Timing of occlusion detection alarms

Basal	Typical time to occlusion detection, hours	Maximum time to occlusion detection, hours
10 U/day	8.5	12.5
25 U/day	3.5	5.5
40 U/day	2.5	3.5

B. Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

The subject device utilizes an insulin pump design that is similar to that of the Omnipod DASH Insulin Management System cleared in K211575. A comprehensive hazard analysis was reviewed in K211575, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed.

As part of this submission, the sponsor provided an updated hazard analysis to account for the unique intended use, design elements, and risks of the Omnipod GO device that were not previously reviewed. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors validation tests were conducted with the Omnipod GO Insulin Delivery Device. All study participants received training that was consistent with the training that patients would receive with the commercial product. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the Omnipod GO Insulin Delivery Device is validated for its intended use.

3. Biocompatibility

All of the materials and manufacturing processes of the proposed Omnipod GO pod patient-contacting and fluid path-contacting components are identical to those of the Omnipod DASH pod (K211575). The differences between the GO and the Omnipod DASH pods are associated with the printed circuit board assembly (PCBA), which is non-patient and non-fluid path-contacting. Therefore, biocompatibility testing previously performed on the fluid path and patient-contacting components of previously cleared versions of this device were leveraged.

Additional testing including in vitro cytotoxicity of the device in its final package, and off-gassing of the GO pod PCBA were performed to ensure product quality and design consistency. The biocompatibility evaluation of the GO Pod PCBAs via off-gas analysis

show no detectable chemical or toxicological concerns and the cytotoxicity study of GO Pods for fluid path components and adhesive pads showed no evidence of in vitro cytotoxicity.

4. Sterility

An EO sterilization product adoption was completed in accordance with AAMI TIR 28:2016. The same sterilization validation method described for the Omnipod DASH device (K211575) continues to be applicable to the subject device. The sterility information was reviewed and found to be acceptable.

5. Insulin Compatibility and Stability

Omnipod GO Pod is compatible with U-100 insulins Novolog, Humalog, Admelog, Fiasp, and Lyumjev just like the Omnipod DASH and Eros systems. No additional insulin compatibility testing was conducted with Omnipod GO Pods as the insulin contacting portions of the Pod is identical to DASH and Eros.

6. Additional Bench Testing

The subject device is evolved from the currently marketed system found in the Omnipod family of Pods including the Omnipod DASH device (K211575) and shares many aspects in product design and requirements. Select verification information of previously cleared Omnipod devices was leveraged for the subject device. Additional verification testing that was conducted specifically for the subject device is as follows:

Shelf Life Test
Battery Life Test
Start Up Conditions Test
Infusion Pressure Test
General Features and Functions Test
Pod Activation, Deactivation and Insulin Delivery Initiation and Termination Test
Environmental Operating Range Test
User Interface Test
Occlusion Release Test

7. Electromagnetic Compatibility and Wireless Coexistence

EMC of the subject device has been evaluated per the following standards:

- IEC 60601-1-2:2020 (ed. 4.1), Medical Electrical Equipment, Part 2: Collateral standard: Electromagnetic compatibility requirements & test
- RTCA DO-160G: 2010 Environmental conditions and test procedures for airborne equipment
- IEC 60601-2-24 Edition 2.0, 2012-10, Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers o Essential performance defined in this particular standard

- IEC 60601-1-11:2015 +A1:2020, 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

All applicable emissions and immunity tests for battery-powered ME equipment were conducted per IEC 60601-1-2:2020 and RTCA DO-160G to demonstrate that the device will perform as expected in the home healthcare environment.

8. Basic Safety and Essential Performance (Electrical Safety)

Insulet provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalence for this device.

9. Software

Detailed information on software of the device was reviewed and found to be acceptable.

10. Cybersecurity

Detailed information on Cybersecurity of the device was reviewed and found to be acceptable.

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.