April 24, 2023

Insulet Corporation
Danna Zylka
Sr. Manager, Regulatory Affairs
100 Nagog Park
Acton, Massachusetts 01720

Re: K223372
Trade/Device Name: Omnipod GO Insulin Delivery Device
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: March 9, 2023
Received: March 10, 2023

Dear Danna Zylka:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K223372

Device Name
Omnipod GO Insulin Delivery Device

Indications for Use *(Describe)*
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.

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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5.0 510(K) SUMMARY

Date prepared:	24-April-2023
510(k) No.	K223372
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park, Acton, MA 01720
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3014585508
Contact Person: **Phone:** **Fax:**	Danna Zylka Sr. Manager, Regulatory Affairs (289) 863-8161 (office) (289) 795-9200 (direct) (978) 600-0120
Device Trade / Proprietary Name:	Omnipod GO Insulin Delivery Device
Device Common Name:	Pump, Infusion, Insulin
Regulation Description:	Infusion pump
Regulation Medical Specialty:	Clinical Chemistry
Review Panel:	Clinical Chemistry
Product Code:	LZG (Infusion Pump)
Submission Type:	Traditional 510(k)
Regulation Numbers:	21 CFR 880.5725
Device Class:	Class II
Predicate device:	K103825, V-GO Insulin Delivery System
Reference device:	K211575, Omnipod DASH Insulin Management System

5.1 Indications 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.

5.2 Device Description

The Omnipod GO Pod helps manage diabetes by providing continuous subcutaneous insulin delivery. To facilitate insulin dose titration and provide appropriate options across a wide range of daily insulin needs, the Omnipod GO Device will come in 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 life of the device. There is no ability to deliver a bolus dose of insulin using the Omnipod GO device. Like the proposed predicate device (V-GO Insulin Delivery System, K103825), Omnipod GO will be entirely self-contained in an on-body device that is single-use, sterile, and disposable. It is small, lightweight, and designed to be attached to the body via an adhesive pad. The adhesive backing keeps the device securely in place for up to 3 days (72 hours).

5.3 Summary of Technological Characteristics Compared to Predicate Device

The subject device has the same intended use (subcutaneous infusion of insulin for the management of diabetes) and similar indications for use, principles of operation, and use environment as the predicate device. Both the subject device and the predicate are prescription only, self-contained, sterile, patient-fillable, single-use disposable devices consisting of a tubeless insulin pump that subcutaneously delivers insulin to a user by automatically pumping insulin to the user at a specified rate over a specified time period. Both the predicate and subject device communicate current device status to the user using visual indicators on the device. The Omnipod GO device additionally communicates device status to the user via audible indicators.

The subject device and predicate device have similar operating principles to achieve the intended therapeutic effect. Both operate by providing force against the insulin reservoir plunger to deliver insulin to the user. The differences between the subject device and predicate device include the following: pumping mechanism, insulin delivery time period (24 hours versus

72 hours), basal delivery rates, insulin delivery accuracy, insulin fill accessory, and alerts and alarm functions. These differences are further described in **Table 1.01** below and are substantiated by including the Omnipod DASH (K211575) as a reference device as the same test methods were used to ensure the safety and effectiveness.

Table 1.01: Predicate Comparison

Element of Comparison	**Predicate Device:** Veritas Inc. V-Go Insulin Delivery Device (K103825)	**Subject Device:** Omnipod GO Insulin Delivery Device
Indications for Use	Indicated for continuous subcutaneous infusion of 20 Units of insulin in one 24-hour time period (0.83U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin. (Note: 30 Unit/day and 40 Unit/day models are also available)	Indicated 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.
Specific Drug/Biologic Use	Rapid-acting U-100 Insulin System has been tested with NovoLog® and Humalog®	Rapid-acting U-100 Insulin System has been tested with NovoLog® Humalog®, Admelog®, Fiasp® and Lyumjev®.
Prescription Status	Prescription Only	Prescription Only
Pumping Mechanism	Mechanical, no software Operate by providing force against a plunger, which is inserted into a cylindrical reservoir filled with high viscosity fluid. This force is directly translated against the rear of the delivery piston at the rear of the insulin reservoir.	Electromechanical, software Step Drive Mechanism is activated by microprocessor; turns leadscrew; presses on syringe style reservoir to deliver insulin through a cannula into a patient's subcutaneous tissue.
Insertion Needle	Integrated 30-gauge stainless steel subcutaneous needle	Integrated 27-gauge stainless steel subcutaneous insertion needle and flexible fluorinated ethylene

Element of Comparison	**Predicate Device:** **Veritas Inc. V-Go Insulin Delivery Device (K103825)**	**Subject Device:** **Omnipod GO Insulin Delivery Device**
		propylene (FEP) infusion cannula
Adhesion to Skin	Secured by an adhesive-backed pad, which is attached to the back of the pump.	Secured by an adhesive-backed pad, which is attached to the back of the pump.
Administrative Sets and Reservoir	Integrated reservoir and patient activated cannula insertion system. No separate infusion set. EZ Fill accessory device used to fill reservoir with insulin.	Integrated reservoir and automatic cannula insertion system. No separate infusion set or reservoir. Fill accessory device used to fill reservoir with insulin.
Basal Insulin Delivery Method and Rates	Once activated, the V-Go device delivers a continuous infusion of insulin at a fixed rate. Device models: 20 Units/24 hr (0.83 U/hr) 30 Units/24 hr (1.25 U/hr) 40 Units/24 hr (1.67 U/hr)	Once activated, the device delivers a continuous infusion of insulin at a fixed rate. Device models: 10 Units/24 hr (0.42 U/hr) 15 Units/24 hr (0.63 U/hr) 20 Units/24 hr (0.83 U/hr) 25 Units/24 hr (1.04 U/hr) 30 Units/24 hr (1.25 U/hr) 35 Units/24 hr (1.46 U/hr) 40 Units/24 hr (1.67 U/hr)
Insulin Delivery Accuracy	+/- 10%	+/- 5%
Bolus Delivery	On – demand with each press of button. Each button press is 2 Units	No bolus delivery
Insulin Delivery Time Period (Useful life)	Each device is specified for # insulin Units/day and is used in a single 24-hour period. 24 hour useful life	Each device is specified for # insulin Units/day and is used for three consecutive days (one 72-hour period). 72 hour useful life

Element of Comparison	**Predicate Device:** **Veritas Inc. V-Go Insulin Delivery Device (K103825)**	**Subject Device:** **Omnipod GO Insulin Delivery Device**
Insulin Status Notifications, Alerts and Alarms	Device does not have any type of notifications or alarms other than a visual gauge indicating reservoir status	Audible and visual (LED) notifications/alerts/alarms Notification Functions: • Pod Activation • Insulin Delivery Advisory Notification/Signal: • Cannula Insertion Countdown • Cannula Insertion Imminent • Cannula Insertion Alert Functions: • Pod Expiration Alarm Functions: • Hazard Alarm • Device Failure Alarm
Occlusion Detection	Viewing window allows visibility of the insulin reservoir and a grey indicator in the window indicates the flow of insulin as demonstrated by the indicator moving over time.	Occlusion algorithm monitors for increased resistance to pumping and alarms if an occlusion is detected within 5 units.
Operating Relative Humidity	20% to 90%	20% to 85%, non-condensing
Operating Temperature	40°F to 99°F (5°C to 37°C)	41°F to 104°F (5°C to 40°C)
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf Life	36 months	18 months

5.4 Standards Compliance

The Omnipod GO Inspire device complies with the following standards as documented in the applicable documents provided in this 510(k) submission.

Standard	Title	Edition in Effect
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process	2018/Cor.1:2010
ISO 10993-3	Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	2014
ISO 10993-5	Biological Evaluation of Medical Devices - Part 5: Tests for in Vitro Cytotoxicity	2009
ISO 10993-6	Biological Evaluation of Medical Devices - Part 6: Test for Local Effects After Implantation	2016
ISO 10993-7	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008/Cor 1:2009
ISO 10993-10	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization	2010
ISO 10993-11	Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity	2017
ISO 10993-12	Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials	2021
ISO 10993-17	Biological Evaluation of Medical Devices - Part 17: Methods for the establishment of allowable limits for leachable substances	2002
ISO 10993-18	Biological Evaluation of Medical Devices - Part 18: Chemical characterization of materials	2020
ISO 11135	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	2014+A1:2018
ISO 11737-1	Sterilization of health care products - microbiological methods - part 1: Determination of a population of microorganisms on product	2018
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2019

Standard	Title	Edition in Effect
ISO 11607-2	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation requirements for forming, sealing and assembly processes	2019
IEC 60601-1-2	Medical Electrical Equipment- Part 1-2: Collateral Standard: Electromagnetic Disturbances - Requirements and Tests	Ed. 4.0: 2014
ISTA 3A	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less	2018
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2016
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	2016
ASTM F88/F88M-15	Standard Test method for Peel Strength of Flexible Barrier Materials	2015
ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressure (Bubble Test)	2019
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Medical Packaging by Dye Penetration	2015
F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	2016
ASTM D903-98	Standard Test method for Peel of Stripping Strength of Adhesive Bonds	2017
IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: Collateral standard: Usability	Ed. 3.1: 2013
IEC 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices	Ed. 1: 2015
ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Ed. 3: 2016
ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	Ed. 2: 2019
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Ed. 3.1: 2012
ANSI/AAMI ES60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	2012
IEC 60601-1-8	Medical Electrical Equipment - Part 1-8: Collateral Standard: Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.	Ed. 2.1: 2012

Standard	Title	Edition in Effect
IEC 60601-1-11	Medical Electrical Equipment - Part 1-11: Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment	Ed. 2.0: 2015
ISO 23908	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	2011
IEC 62304	Medical Devices Software - (Software life cycle processes)	Ed. 1.1: 2015

5.5 Summary of Non-Clinical Performance Data

Performance testing on the Omnipod GO device included the following:

- **Risk Management:** Risk management was completed in accordance with ISO14971:2019. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met, and the device is safe for use.
    - **Safety Assurance:** The Omnipod GO device utilizes an insulin pump design that has been marketed with other Omnipod devices (Omnipod and Omnipod DASH Insulin Management Systems, pre-market filing (K211575). The Omnipod GO device features and functions have been significantly simplified from the previously marketed devices to serve the intended user and application. The notable difference in the Omnipod GO device is the absence of a controller device which is employed in the Omnipod and Omnipod DASH systems to set up insulin delivery parameters, program bolus dosing by the user and provide device status information. The majority of risk mitigations in the Omnipod and Omnipod DASH Pods related to insulin delivery are similarly implemented in the Omnipod GO device to provide safety against overdose and under dose situations (such as occlusion detection and delivery accuracy).
- **Human Factors Validation:** Insulet executed a comprehensive human factors and usability engineering process that followed and complied with the FDA-recognized standards IEC 62366:2015-1 and HE75:2009 as well as the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices –Issued February 3, 2016. A robust validation evaluation was performed to demonstrate safe and effective use of the Omnipod GO device with intended users in the expected use

environments, including associated training and accompanying documentation. The results of the validation demonstrate that the Omnipod GO has been found to be safe and effective for the intended users, uses, and use environments.

- **Software Validation:** Software verification and validation testing was performed in accordance with IEC 62304:2015 and FDA's guidance document, General Principles of Software Validation – Issued January 11, 2002.
- **Cybersecurity:** A cybersecurity analysis was performed for the Omnipod GO device following the FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical devices – Issued October 18, 2020, and the principles outlined in the FDA guidance, Postmarket Management of Cybersecurity in Medical Devices – Issued December 28, 2020. Insulet has provided a software bill of materials and penetration testing.
- **Performance Testing:** Verification testing has demonstrated that the device delivers insulin accurately at various flow rates and that it can effectively detect when an occlusion occurs and promptly notify the user.
- **Biocompatibility:** All patient-contacting materials and manufacturing processes of the Omnipod GO device are the same as those of the currently marketed Omnipod Pod devices. A biocompatibility evaluation was performed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.
- **Sterilization:** A product adoption was completed to adopt the Omnipod GO device into the family of devices under the sterilization validation.
- **Electrical Safety and EMC Testing:** Testing was performed to verify that the Omnipod GO device meets its requirement to comply with IEC 60601-1: 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: Collateral Standard: Electromagnetic Disturbances-Requirements and Tests.

5.6 Substantial Equivalence Conclusion

After analyzing the intended use/indications for use, technological characteristics, and performance data, Insulet concludes that the Omnipod GO Insulin Delivery Device is substantially equivalent to the legally marketed Valeritas Inc. V-Go Insulin Delivery Device (K103825). While the subject device's technological characteristics differ slightly from the predicate, the differences do not raise different questions of safety and effectiveness as substantiated by the reference device (Omnipod DASH device cleared under K211575). Therefore, the Omnipod GO is substantially equivalent to the predicate device.