January 27, 2022

Insulet Corporation
Alexander Hamad
Regulatory Affairs Specialist
100 Nagog Park
Acton, MA 01720

Re: K203768
Trade/Device Name: Omnipod 5 ACE Pump (Pod)
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG
Dated: September 2, 2021
Received: September 3, 2021

Dear Alexander Hamad:

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)*
K203768

Device Name
Omnipod 5 ACE Pump (Pod)

Indications for Use *(Describe)*
The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE 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 Omnipod 5 ACE Pump is intended for single patient, home use and requires a prescription.

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

510(K) SUMMARY

Date Prepared:	January 27, 2022
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:**	Alexander Hamad Sr. Regulatory Affairs Specialist 978-600-2432 (Office) 978-600-0120
Device Trade/Proprietary Name:	Omnipod 5 ACE Pump (Pod)
Device Common Name:	Omnipod 5 ACE Pump
Regulation Description:	Alternate Controller Enabled Insulin Infusion Pump
Review Panel(s):	Clinical Chemistry
Product Code(s):	QFG
Regulation Numbers:	21 CFR 880.5730
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	K191679, Omnipod DASH Insulin Management System with Interoperable Technology

Device Description:

The Omnipod 5 alternate controller enabled (ACE) Pump is intended to deliver insulin via a tubeless insulin pump (the Pod) that wirelessly connects to and receives insulin delivery commands from the Omnipod 5 Application (App), which is installed on a locked-down controller device or a user's personal compatible smartphone device.

The Omnipod 5 ACE Pump is part of the Omnipod 5 Automated Insulin Delivery System, which also includes the Omnipod 5 Interoperable Automated Glycemic Controller (iAGC), Omnipod 5 Bolus Calculator, and the third-party Dexcom G6 iCGM. Omnipod 5 iAGC and Bolus Calculator functions are functionally independent from the Omnipod 5 ACE Pump. The Omnipod 5 ACE Pump is intended to be digitally connected to the iCGM, the iAGC, and the Bolus Calculator.

The Omnipod 5 ACE Pump can operate in Manual Mode, delivering insulin based on user-programmed basal rates, or in Automated Mode, where insulin is automatically delivered based on the calculations and command of a compatible iAGC. Currently, the Omnipod 5 ACE Pump is compatible with the Omnipod 5 iAGC, whose software is pre-installed on the Pod and the App. Future alternate controllers (iAGCs) may be established for use with the Pod, in which case the software modules of the Omnipod 5 iAGC would be disabled.

The Pod is a body-wearable insulin pump that affixes to the user on the back of the arm, the lower back, the 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 Omnipod 5 App is an Android software application installed on a handheld touchscreen device that connects to the Pod via Bluetooth Low Energy (BLE) and serves as the user interface of the system.

In addition to programmed basal delivery and automated insulin delivery, the Omnipod 5 ACE Pump allows users to deliver bolus doses at values that are either inputted manually or calculated by the Omnipod 5 Bolus Calculator based on the user's settings and user-entered parameters. The Pod has the ability to connect to a compatible iCGM through BLE and receive data for use with the Omnipod 5 iAGC and Omnipod 5 Bolus Calculator.

The Omnipod 5 App has the ability to wirelessly connect to the Insulet Cloud which it utilizes for registering new devices, authenticating users, ensuring hardware devices and host operating systems are compatible, and completing over the air software (OTA) and firmware (FOTA) updates. In addition, data from the App uploads regularly to the Insulet Cloud for data management purposes.

Summary of Technological Characteristics Compared to Predicate Device:

The subject device and predicate device use the same operating principles to achieve the intended therapeutic effect. The subject device has the same intended use and similar indications for use, principles of operation, and use environment as the predicate device. The subject device and predicate device are both software-controlled, programmable ACE pumps capable of both basal and bolus delivery of insulin.

The differences between the subject device and predicate device with respect to the Pod include additional hardware components on the Printed Circuit Board Assembly (PCBA) and additional software to optimize compatibility with the iAGC. All aspects of the Pod related to patient and drug contacting materials and components, as well as the mechanical aspects for cannula deployment and insulin delivery, are identical. The differences between the subject device and predicate device on the App side include an update to the user interface, additional screens used for connection to iCGM and automated delivery, and the ability to be installed and operated on a user's personal compatible smartphone, as an alternative to the locked-down device.

The differences between predicate and subject device do not raise any different questions about safety and effectiveness, and performance data demonstrates the Omnipod 5 ACE Pump is substantially equivalent to its predicate. **Table 1** below illustrates the equivalence of the subject device to the predicate.

Table 1. Substantial Equivalence Comparison

Element of Comparison	**Subject Device:** **Omnipod 5 ACE Pump**	**Predicate Device:** **Omnipod DASH™ Insulin Management System (K191679)**
Indications for Use	The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The ACE 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 ACE Pump is intended for single patient, home use and requires a prescription.	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.
Pump Type	Alternate controller enabled (ACE) infusion pump	Alternate controller enabled (ACE) infusion pump
Specific Drug/Biologic Use	U-100 Insulin System has been tested with NovoLog®, Humalog®, and Admelog®	U-100 Insulin System has been tested with NovoLog® Humalog®, Apidra®, and Admelog®
Prescription Status	Prescription Device	Prescription Device
Labeling	Package Labels, User's Guide (contains Instructions for Use)	Package Labels, User's Guide (contains Instructions for Use)
Component and Accessories	OP5 Pod (insulin pump), hand- held OP5 Controller/or user's smartphone (interoperable controller) fill-needle and fill syringe.	DASH Pod (insulin pump), hand-held DASH PDM (interoperable controller), fill-needle and fill syringe
Communication with compatible iAGC	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)

Element of Comparison	**Subject Device:** **Omnipod 5 ACE Pump**	**Predicate Device:** **Omnipod DASH™ Insulin Management System (K191679)**
Controller host device	Controlled by OP5 Locked Down Controller or user's compatible mobile smartphone with OP5 App installed	Controlled by DASH PDM (Locked Down Controller)
Pumping Mechanism	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.	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.
Administrative Sets and Reservoir	Integrated reservoir and patient activated cannula insertion system. No separate infusion set or reservoir.	Integrated reservoir and patient activated cannula insertion system. No separate infusion set or reservoir.
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.	Basal: 0.05 - 30 units/hour in 0.05 unit increments. Bolus: 0.05 - 30 units in 0.05 unit increments.
Maximum Bolus Flow Rate	1.5 units per minute	1.5 units per minute
Delivery Accuracy (tested per IEC 60601-2-24)	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
Pump Software	Pod-Controller communication via Bluetooth Pod-CGM communication via Bluetooth Software to host iAGC	Pod-PDM communication via Bluetooth
Power Requirements	Disposable Batteries – Pod	Disposable Batteries - Pod
Fluid Pathway Materials	• Fluorinated Ethylene Propylene (FEP) • Dimethylmethyl 3,3,3-trifluoropropyl siloxane • Stainless Steel • Polydimethylsiloxane • Polypropylene (PP) • Cyclic Olefin Copolymer (COC) • Polyethylene (PE)	• Fluorinated Ethylene Propylene (FEP) • Dimethylmethyl 3,3,3-trifluoropropyl siloxane • Stainless Steel • Polydimethylsiloxane • Polypropylene (PP) • Cyclic Olefin Copolymer (COC) • Polyethylene (PE)

Element of Comparison	**Subject Device:** **Omnipod 5 ACE Pump**	**Predicate Device:** **Omnipod DASH™ Insulin Management System (K191679)**
Alarms and Alerts	Alarm Types: • Pod: Audible • Controller: Visible, vibratory, audible (dependent on settings) Alarms: • Low Reservoir • Resume Insulin • Controller Software/Hardware Failure • Pod Software/Hardware Failure • Empty Reservoir • Occlusion Detected • Pod Expiration • Auto Off • Urgent Low Glucose • Missing CGM Values	Alarm Types: • Pod: Audible • PDM: Visible, vibratory, audible Alarms: • Low Reservoir • Resume Insulin • PDM Software/Hardware Failure • Pod Software/Hardware Failure • Empty Reservoir • Occlusion Detected • Pod Expiration • Auto Off
Safety Functions	• Safety Checks • Continuous System Monitoring • Occlusion Detection	• Safety Checks • Continuous System Monitoring • Occlusion Detection
Occlusion Detection Algorithm	Detects occlusion at 5.0 units.	Detects occlusion at 5.0 units
Operating Relative Humidity	20 to 85%	20 to 85%
Operating Temperature	41°F to 104°F (5°C to 40°C)	41°F to 104°F (5°C to 40°C)
Memory	Pod events are relayed to OP5 Controller. Events are stored on Controller for up to 90 days.	Pod events are relayed to PDM. Events are stored on PDM for up to 90 days.
Sterilization	Pod: EO	Pod: EO
Shelf life	Pod: 18 months	Pod: 18 months

Standards Compliance

The Omnipod 5 ACE Pump (Pod) complies with the following standards as documented in the applicable documents provided in this 510(k) submission.

- IEC 62366-1:2015 – Medical Devices – Part 1: Application of Usability Engineering
- ISO 14971:2007 – Medical devices – Application of Risk Management to Medical Devices
- IEC 62304 Ed. 1.1 2015 – Medical device software – Software life cycle processes
- IEC 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
- IEC 60601-1-2: 2014 – Medical Electrical Equipment – Part 1-2: Collateral Standard: Electromagnetic Disturbances- Requirements and Tests
- IEC 60601-1-6:2013 – Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2012 – Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2015 – Medical electrical equipment - Part 1-11: 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
- ISO 10993-1: 2018– Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009 – Biological Evaluation of medical devices – Part 5: Cytotoxicity study using the ISO direct contact method
- ISO 10993-18: 2020 – Biological Evaluation of Medical Devices – Part 18 Chemical Characterization of Materials
- ISO 10993-17: 2002 – Biological evaluation of medical devices Part 17: Establishment of Allowable Limits for Leachable Substances
- ISO 10993-12: 2012 – Biological Evaluation of Medical Devices - Part 12 Sample Preparation of Reference Materials

Summary of Non-Clinical Performance Data

The Omnipod 5 ACE Pump (Pod) is identical to the Omnipod DASH Pod (K191679), with the only modifications being the Printed Circuit Board Assembly (PCBA) and software modifications to optimize compatibility with the iAGC. Performance testing on the Omnipod 5 ACE Pump included the following:

- **Risk Management:** Risk management was completed in accordance with ISO 14971:2007. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the device is safe for use.
- **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 5 ACE Pump with intended users in the expected use environments, including associated training and accompanying documentation. The results of the validation demonstrate that the Omnipod 5 ACE Pump 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.
    - **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.
    - **Data Logging:** Software verification testing has demonstrated the device records timestamped critical events, including information related to its state, user inputs, and device settings, as required by the special controls.
    - **Interoperability:** Interoperability documentation was provided according to the FDA Guidance Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff – Issued September 6, 2017 and specifies validated interface specifications to potential

interoperable devices and partnership agreements regarding contractual issues, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities.

- **Cybersecurity:** A cybersecurity analysis was performed for the Omnipod 5 ACE Pump using 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.

- **Biocompatibility:** All patient-contacting materials and manufacturing processes of the Omnipod 5 ACE Pump (Pod) are the same as those of the currently marketed Omnipod DASH System. Therefore, previous biocompatibility testing of the predicate device is still applicable.
- **Sterilization:** A product adoption was completed to adopt the Omnipod 5 ACE Pump into the family of devices under the sterilization validation.
- **Electrical Safety and EMC Testing:** Testing was performed to verify that the Omnipod 5 ACE Pump 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.
- **Special Controls:** Evaluation of the Special Controls for this device (regulation 21 CFR 880.5730) assures the safety and effectiveness of the device.

Substantial Equivalence Conclusion

After analyzing the intended use/indications for use, technological characteristics, and performance data, Insulet concludes that the Omnipod 5 ACE Pump is substantially equivalent to the legally marketed Omnipod DASH Insulin Management System with Interoperable Technology. While the subject device's technological characteristics, namely the PCBA hardware components and software modules differ slightly from the predicate, the differences do not raise different questions of safety and effectiveness. Therefore, the Omnipod 5 ACE Pump is substantially equivalent to the predicate device.