October 18, 2023

Insulet Corporation
Maria Brower
Senior Specialist Regulatory Affairs
100 Nagog Park
Acton, MA 01720

Re: K231826
Trade/Device Name: Omnipod 5 ACE Pump
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: September 18, 2023
Received: September 19, 2023

Dear Maria Brower:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
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)*
K231826

Device Name
Omnipod 5 ACE Pump

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
maker of Omnipod

K231826 510(K) SUMMARY

Date prepared:	October 16, 2023
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park, Acton, MA 01720
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3014585508
Primary Contact Person **Phone:** **Secondary Contact Person** **Phone:** **Fax:**	Maria Brower, Senior Specialist, Regulatory Affairs, Digital Health 978-600-7000 Katie Pacheco, Director Regulatory Affairs, Digital Health 978-600-7000 978-600-0120
Device Trade / Proprietary Name:	Omnipod 5 ACE Pump (Pod)
Device Common Name:	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:	K203768 (Omnipod 5 ACE Pump)

5.1 Purpose of Submission

The Omnipod 5 alternate controller enabled (ACE) Pump is being modified to add a new mobile application which is compatible with iOS mobile devices. The Omnipod 5 App (iOS) is the new configuration being added to the previously cleared Omnipod 5 ACE Pump.

5.2 Intended Use and 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 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.

5.3 Device Description

The Omnipod 5 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 App, which is installed on a locked-down Android controller device or a user's personal smartphone device. The predicate device allowed the user to download the Omnipod 5 App to an Android compatible phone. This submission includes an iOS compatible Omnipod 5 App to allow users to download it to a compatible iPhone.

The Omnipod 5 ACE Pump is part of the Omnipod 5 Automated Insulin Delivery System, which also includes SmartAdjust Technology (iAGC), and the SmartBolus Calculator. SmartAdjust Technology and the SmartBolus Calculator functions are functionally independent from the Omnipod 5 ACE Pump. The Omnipod 5 ACE Pump is intended to be digitally connected to a third party iCGM, SmartAdjust Technology, and the SmartBolus 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 SmartAdjust Technology, the software which is pre-installed on the Pod and

the App. Future alternate controllers may be established for use with the Pod, in which case the software modules of the SmartAdjust Technology 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 a software application installed on a handheld touchscreen device (Android and iOS) 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 SmartBolus 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 SmartAdjust Technology and the SmartBolus 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.

Summary of Technological Characteristics Compared to Predicate Device

The Omnipod 5 ACE Pump, with Android and iOS compatible Omnipod 5 Apps, (Subject Device) has been developed with the intent of providing the Omnipod 5 App features equivalent to the predicate device to end users. There are no changes to the intended use and indications for the Omnipod 5 ACE Pump. Due to the different mobile operating system platforms, technical differences between the applications exist, such as different programming languages, user interface, and navigation to align with iOS guidelines. There have been no modifications to the Omnipod 5 Pod or the Omnipod 5 App (Android) for the addition of the iOS compatible app.

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 5.01** below illustrates the equivalence of the subject device to the predicate.

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Table 5.01: Omnipod 5 ACE Pump Substantial Equivalence Comparison

Element of Comparison	Subject Device: Omnipod 5 ACE Pump	Predicate Device: Omnipod 5 ACE Pump (K203768)
Intended use/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 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.	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.
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®, and Admelog®
Prescription Status	Prescription Device	Prescription Device
Component and Accessories	Omnipod 5 Pod (insulin pump), hand-held Omnipod 5 Controller/or user's smartphone (interoperable controller) fill-needle and fill syringe.	Omnipod 5 Pod (insulin pump), hand-held Omnipod 5 Controller/or user's smartphone (interoperable controller) fill-needle and fill syringe.
Communication with Compatible iAGC	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)
Omnipod 5 App host device	Hosted by Omnipod 5 Locked Down Android Controller or user's compatible mobile smartphone (Android or iPhone) with Omnipod 5 App installed.	Hosted by Controlled by Omnipod 5 Locked Down Android Controller or user's compatible mobile smartphone (Android) with Omnipod 5 App installed.

Element of Comparison	Subject Device: Omnipod 5 ACE Pump	Predicate Device: Omnipod 5 ACE Pump (K203768)
Omnipod 5 App Operating System	iOS and Android Operating System	Android Operating System
Pod 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.
Pod 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.
Pod 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.
Pod Maximum Bolus Flow Rate	1.5 units per minute	1.5 units per minute
Pod 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
Pod Software	Pod-Controller communication via Bluetooth Pod-CGM communication via Bluetooth Software to host iAGC	Pod-Controller communication via Bluetooth Pod-CGM communication via Bluetooth Software to host iAGC
Power Requirements	Disposable Batteries – Pod	Disposable Batteries – Pod

Element of Comparison	Subject Device: Omnipod 5 ACE Pump	Predicate Device: Omnipod 5 ACE Pump (K203768)
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)
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 • 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
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)

Element of Comparison	Subject Device: Omnipod 5 ACE Pump	Predicate Device: Omnipod 5 ACE Pump (K203768)
Memory	Pod events are relayed to Omnipod 5 App. Events are stored on the App for up to 90 days.	Pod events are relayed to Omnipod 5 App. Events are stored on App for up to 90 days.
Pod Sterilization	Pod: EO	Pod: EO
Shelf life	Pod: 18 months	Pod: 18 months

5.4 Standards Compliance

The Omnipod 5 ACE Pump with Omnipod 5 App(iOS) complies with the following standards in relation to the proposed change within this submission:

Standard	Title	FDA Recognition No.
ANSI AAMI ISO 14971:2019	Medical devices – Application of Risk Management to Medical Devices	5-125
IEC 62304:2015-06	Medical Devices Software - (Software life cycle processes)	13-79
IEC 60601-1-2:2020-07	Medical Electrical Equipment- Part 1-2: Collateral Standard: Electromagnetic Disturbances - Requirements and Tests	19-36
IEC 60601-1:2020-08	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	19-49
IEC 60601-1-6:2020-07	Medical Electrical Equipment - Part 1-6: Collateral standard: Usability	5-132
IEC 60601-1-8:2020-07	Medical Electrical Equipment - Part 1-8: Collateral Standard: Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.	5-131
IEC 60601-1-10:2020-07	Medical Electrical Equipment - Part 1-10: Collateral Standard: Requirements for the development of physiologic closed-loop controllers	19-37

Standard	Title	FDA Recognition No.
IEC 60601-1-11:2020-07	Medical Electrical Equipment - Part 1-11: Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment	19-38
ANSI AAMI IEC 62366-1:2015-06	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices	5-129
ANSI AAMI HE75:2009/(R)2018	Human Factors Engineering – Design of Medical Devices	5-57

5.6 Summary Non-Clinical Performance Data

Performance testing was focused primarily on software verification and validation for the Omnipod 5 App and at the system level. No performance testing applicable only to the OP5 Pod was completed as the Pod has not been modified.

Performance testing for the addition of an iOS compatible Omnipod 5 App included the following:

- Risk Management: risk management was completed in accordance with ISO 14971:2019. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the device is safe for use.

- Software Validation: software verification and validation testing were performed in accordance with IEC 62304:2015-06 and FDA's guidance document, *General Principles of Software Validation* – Issued January 11, 2002. Software documentation was provided in accordance with FDA guidance *Content of Premarket Submissions for Device Software Functions* - Issued June 2023.

    - 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 ACE Pump special controls.

- Interoperability: Interoperability documentation was provided as is relates to changes due to the Omnipod 5 App (iOS) 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. It 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 OP5 ACE Pump with the Omnipod 5 App (iOS) using the FDA guidance, *Content of Premarket Submissions for Management of Cybersecurity in Medical devices* – Issued 2014, the principles outlined in the FDA guidance, *Postmarket Management of Cybersecurity in Medical Devices*, – Issued 2016, and *Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act* – Issued March 30, 2023 and *Cybersecurity in Medical Devices: Quality System Considerations and Content Premarket Submission DRAFT guidance for Industry and FDA Staff* –April 2022. In addition, Insulet has provided a software bill of materials and penetration testing.

- Electrical Safety and EMC Testing: testing was performed to verify that the Omnipod 5 ACE Pump with the Omnipod 5 App (iOS) meets its requirement to comply with IEC 60601-1:2020-08 (Consolidated Version) Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-2:2020-9 Medical Electrical Equipment – Part 1-2: Collateral Standard: Electromagnetic Disturbances- Requirements and Tests. Guidances *Electromagnetic Compatibility (EMC) of Medical Devices* Issued June 6, 2022 and *Radio Frequency Wireless Technology in Medical Devices* -Issued August 14, 2013.

- Human Factors Validation: Insulet executed a comprehensive human factors and usability engineering process that followed and complied with the FDA-recognized standards IEC 62366:2015-06 and HE75:2009(R)2018 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 App (iOS) with intended users in the expected use environments, including associated training and accompanying documentation. The results of the validation demonstrate that the device has been found to be safe and effective for the intended users, uses, and use environments.

- Special Controls: evaluation of the Special Controls for this device (regulation 21 CFR 880.5730) supports the safety and effectiveness of the device.

5.7 Conclusion

The Omnipod 5 ACE Pump, with the addition of the iOS compatible Omnipod 5 App, has the same intended use and indications for use as the predicate device. The differences in technological characteristics of the subject device compared to the predicate device do not raise different questions of safety and effectiveness. Through performance testing, the Subject device has been shown to meet the Alternate Controller Enabled Insulin Pump special controls and determined to be substantially equivalent to its predicate.