December 3, 2025

Insulet Corporation
Alexander Hamad
Manager, Regulatory Affairs
100 Nagog Park
Acton, Massachusetts 01720

Re: K251779
Trade/Device Name: Omnipod 5 algorithm
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJI
Dated: June 9, 2025
Received: June 10, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251779

Please provide the device trade name(s).

Omnipod 5 algorithm

Please provide your Indications for Use below.

The Omnipod 5 algorithm is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 algorithm is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. The Omnipod 5 algorithm is intended for single patient use and requires a prescription.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Insulet
maker of Omnipod

510(k) Summary

Submission Number	K251779
Date prepared:	November 28, 2025
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:** **Fax:**	Alexander Hamad Manager, Regulatory Affairs 978-600-2432 978-600-0120
Device Trade / Proprietary Name:	Omnipod 5 algorithm
Device Common Name:	Interoperable Automated Glycemic Controller
Review Panel (s):	Clinical Chemistry
Product Code(s):	QJI
Regulation Numbers:	21 CFR 862.1356
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	K241777 (SmartAdjust™ technology)

Insulet
maker of Omnipod

1. Intended Use and Indications for Use

The Omnipod 5 algorithm is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 algorithm is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. The Omnipod 5 algorithm is intended for single patient use and requires a prescription.

2. Device Description

The Omnipod 5 algorithm is a software-only device that enables automated insulin delivery by taking in glucose inputs from a connected iCGM and calculating insulin micro-bolus outputs for delivery by a connected ACE Pump.

The Omnipod 5 algorithm is part of the Omnipod 5 Automated Insulin Delivery System, which also includes the Omnipod 5 ACE Pump and the SmartBolus Calculator regulated devices. The Omnipod 5 ACE Pump and the SmartBolus Calculator are functionally independent from the Omnipod 5 algorithm. The Omnipod 5 algorithm is intended to be digitally connected to a third party iCGM, the Omnipod 5 ACE Pump, and the SmartBolus Calculator.

The Omnipod 5 algorithm software is installed on both the Omnipod 5 Pod and Omnipod 5 App (either installed on a compatible smartphone or on the Insulet provided Controller) to comprise the Omnipod 5 System. As all regulated devices are required for the Omnipod 5 System, a prescription for the Omnipod 5 System and Omnipod 5 Pods includes:

- Omnipod Pods with Omnipod 5 algorithm software and
- Omnipod 5 Application with Omnipod 5 algorithm and SmartBolus Calculator software provided on Insulet provided Controller and when installed on the user's personal mobile device.

The Omnipod 5 System is a hybrid closed loop system and therefore can operate in either open loop (Manual Mode; Omnipod 5 algorithm disabled) or closed loop (Automated Mode; Omnipod

5 algorithm enabled). When Automated Mode is turned on, the Omnipod 5 algorithm (installed on the Pod) controls insulin delivery based on recent CGM values.

3. Summary of Technological Characteristics Compared to Predicate

Please refer to **Table 1** below for a substantial equivalence table, which includes a comparison of the technological characteristics between the subject device and its predicate.

Table 1. Omnipod 5 Algorithm Substantial Equivalence Comparison

Element of Comparison	Subject Device: The Omnipod 5 algorithm	Predicate Device: SmartAdjust technology (K241777)
Intended use/indications for use	The Omnipod 5 algorithm is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 algorithm is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years or age and older. The Omnipod 5 algorithm is intended for single patient use and requires a prescription	SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. SmartAdjust™ technology is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years or age and older. SmartAdjust™ technology is intended for single patient use and requires a prescription
Device Type	Interoperable automated glycemic controller	Interoperable automated glycemic controller
Environment of use	Ambulatory use	Ambulatory use
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®

Element of Comparison	Subject Device: The Omnipod 5 algorithm	Predicate Device: SmartAdjust technology (K241777)
Prescription Status	Prescription Device	Prescription Device
Principles of Operation	Algorithmic software device intended to automatically increase, decrease, and pause delivery of insulin based on iCGM readings and predicted glucose values	Algorithmic software device intended to automatically increase, decrease, and pause delivery of insulin based on iCGM readings and predicted glucose values
Communication and Pairing	Bluetooth Low Energy (BLE) wireless technology	Bluetooth Low Energy (BLE) wireless technology
Device Hosting Controller	Omnipod 5 ACE Pump	Omnipod 5 ACE Pump
Digitally Connected Devices	Cleared iCGM and ACE Pump, which includes a display device (Insulet-provided Controller phone or user's compatible smartphone)	Cleared iCGM and ACE Pump, which includes a display device (Insulet-provided Controller phone or user's compatible smartphone)
System Functionality Modes	• The Omnipod 5 algorithm enabled (Automated Mode): closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values • The Omnipod 5 algorithm not enabled (Manual Mode): open loop, basal delivery based on user-defined programs	• The Omnipod 5 algorithm enabled (Automated Mode): closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values • The Omnipod 5 algorithm not enabled (Manual Mode): open loop, basal delivery based on user-defined programs
Alarms/Alerts	• Out of Range Alert • Low Alert *(ACE Pump)* • Maximum Insulin Delivery Alert	• Out of Range Alert • Low Alert *(ACE Pump)* • Maximum Insulin Delivery Alert
Alert/Alarm Display	ACE Pump alarms/alerts will be displayed and communicated tothe user via visual, audible, and/or vibratory cues.	ACE Pump alarms/alerts will be displayed and communicated to the user via visual, audible, and/or vibratory cues.
Target Glucose	100-150 mg/dl, user-customizable	110-150 mg/dl, user-customizable

Element of Comparison	Subject Device: The Omnipod 5 algorithm	Predicate Device: SmartAdjust technology (K241777)
Control Range		
Mechanism of Software Update	Firmware over the Air	Firmware over the Air
History Storage	Up to 90 days (user insulin history)	Up to 90 days (user insulin history)
Labeling	Package Labels, User's Guide (contains Instructions for Use), Technical User Guide	Package Labels, User's Guide (contains Instructions for Use), Technical User Guide

4. Summary of Non-Clinical Performance Testing

- Software V&V: 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. Software documentation was provided in accordance with FDA guidance document *Content of Premarket Submissions for Device Software Functions* – issued June 14, 2023.
    - Interoperability: Interoperability documentation was provided as it relates to changes to the Omnipod 5 algorithm according to the FDA guidance document *Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff* – Issued September 6, 2017.
- In Silico Clinical Study: Performance Validation was conducted via an in silico clinical trial. Details of the study were provided in accordance with the FDA guidance document *Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions* – issued November 17, 2023. The study concludes that the simulated performance of Omnipod 5 with the 100 mg/dL target as compared to the real-world performance of Omnipod 5 with the 110 mg/dL target meets the acceptance criteria for non-inferiority and demonstrates substantial equivalence to the predicate device.
- Special Controls: evaluation of the Special Controls for this device (regulation 21 CFR 862.1356) supports the safety and effectiveness of the device.

5. Conclusion

The Omnipod 5 algorithm has the same intended use and indications for use as the predicate device. The Omnipod 5 algorithm has the same technological characteristics and principles of operation as the predicate device. The software has been updated to add 100 mg/dL as a target glucose value input to the Algorithm and to modify the ADR alert to improve user experience and allow users to remain in Automated Mode after acknowledging the Alert. These modifications to the design do not raise different questions of safety and effectiveness. The changes to the software are supported by in silico clinical validation and design verification and validation which demonstrate that the subject device and predicate device are substantially equivalent. Product labeling has been updated to reflect the changes to the software, add a summary of the in silico clinical trial, and update the name of the device. The differences between the predicate and subject devices do not raise any different questions about safety and effectiveness, therefore, the Omnipod 5 algorithm is substantially equivalent to its predicate.