June 29, 2026

Insulet Corporation
Lavanya Ramnath
Senior Regulatory Affairs Specialist
100 Nagog Park
Acton, Massachusetts 01720

Re: K261461
Trade/Device Name: Omnipod 6 algorithm
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI
Dated: May 1, 2026
Received: May 4, 2026

Dear Lavanya Ramnath:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K261461

Please provide the device trade name(s).

Omnipod 6 algorithm

Please provide your Indications for Use below.

The Omnipod 6 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 6 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 6 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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

510(k) Submitter Information

Submitter's Name and Address	Insulet Corporation 100 Nagog Park Acton, MA 01720, USA
FDA Establishment Owner/Operator Number	9056196
FDA Establishment Registration Number	3014585508
Primary Contact Person	Lavanya Ramnath Senior Regulatory Affairs Specialist Tel: +1 213-326-6706 Email: lramnath@insulet.com
Date prepared	June 29, 2026

Device Information:

Submission number	K261461
Device Trade / Proprietary Name	Omnipod 6 algorithm
Device Common Name	Interoperable Automated Glycemic Controller (iAGC)
Review Panel (s)	Clinical Chemistry
Product Code(s)	QJI
Regulation Numbers	21 CFR 862.1356
Submission Type	Traditional 510(k)
Device Class	Class II
Predicate Device	K251779, Omnipod 5 algorithm

Insulet
maker of Omnipod

1. Intended Use and Indications for Use

The Omnipod 6 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 6 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 6 algorithm is intended for single patient use and requires a prescription.

2. Device Description

The Omnipod 6 Automated Insulin Delivery (AID) System is comprised of 3 regulated devices: Omnipod 6 algorithm (iAGC), Omnipod 6 ACE Pump and SmartBolus Calculator; and is interoperable with a third-party manufactured continuous glucose monitor (CGM).

The subject device, the Omnipod 6 algorithm (iAGC) is a software-only device that is intended for use by people with type 1 diabetes in persons 2 years of age and older and type 2 diabetes in persons 18 years of age and older. The Omnipod 6 algorithm enables automated insulin delivery by receiving inputs from a connected CGM, calculates insulin micro-bolus outputs every 5 minutes based upon the predicted glucose over a 60-minute prediction horizon for insulin delivery by a connected ACE Pump. The Omnipod 6 algorithm delivers autocorrection micro-boluses every five minutes and personalizes insulin delivery based on the user's bolus behavior and past trends. This design supports a wide range of bolus behaviors by increasing automated insulin delivery when needed.

The Omnipod 6 algorithm resides on both the Omnipod 6 Pod and Omnipod 6 App (either installed on a compatible smartphone or on the Insulet provided Controller)

The Omnipod 6 System is a hybrid closed loop system and therefore can operate in either open loop (Manual Mode) or closed loop (Automated Mode).

In Manual Mode, the Omnipod 6 algorithm (iAGC) is disabled and basal insulin delivery is based on user-defined basal programs (per HCP guidance) and bolus insulin is based on user request and inputs which may be informed by the SmartBolus Calculator. Manual mode operation does not require a connected CGM.

In Automated Mode, the Omnipod 6 algorithm (iAGC, installed on the Pod) is enabled; controls insulin delivery based on user's set glucose target, recent CGM values and automatically adjusted adaptive rate personalized to user insulin history and bolus behavior. Automated Mode operation requires connected CGM. When the Omnipod 6 algorithm (iAGC is enabled), Automated Mode has 3 states of operation:

- Automated Mode: System calculates insulin delivery every 5 minutes based on the user-customizable glucose target (100–150 mg/dL).
- Automated: Limited Mode: Enabled when the Omnipod 6 algorithm (iAGC) is not receiving data from a connected CGM for 20 minutes or more or during sensor warm-up. While in Limited Mode, the user will receive basal insulin at or below either the pre-programmed basal rate or the rate based on past insulin usage, whichever is less. Once the iAGC and CGM are reconnected and a valid EGV is received from the CGM, the system will resume delivery of insulin in Automated Mode.
- Activity Feature: Intended for use during periods when insulin sensitivity is expected to be higher, such as during exercise. The feature can be set for various time durations during Automated Mode. With Activity, the algorithm reduces insulin delivery by setting a temporary glucose target to 150 mg/dL. Activity Feature has a maximum selectable duration of 24 hours.

As all regulated devices are required for the operation of the Omnipod 6 AID System, a prescription includes:

- Omnipod Pods with Omnipod 6 algorithm software and

- Omnipod 6 Application with Omnipod 6 algorithm and SmartBolus Calculator software provided on-Insulet provided Controller and when installed on the user's personal mobile device.

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 6 Algorithm Substantial Equivalence Comparison

Element of Comparison	Subject Device: The Omnipod 6 algorithm	Predicate Device: The Omnipod 5 algorithm
Intended use/indications for use	The Omnipod 6 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 6 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 6 algorithm is intended for single patient use and requires a prescription	Identical, except for device name change (from Omnipod 5 algorithm to Omnipod 6 algorithm)
Device Type	Interoperable automated glycemic controller (iAGC), software-only device	Identical
Regulatory Classification	Class II (21 CFR 862.1356)	Identical
Product code	QJI	Identical

Element of Comparison	Subject Device: The Omnipod 6 algorithm	Predicate Device: The Omnipod 5 algorithm
Environment of use	Ambulatory use	Identical
Specific Drug/Biologic Use	U-100 Insulin System has been tested with and is compatible with NovoLog®, Humalog®, Admelog® and Kirsty®	Identical
Prescription Status	Prescription is required	Identical
Principles of Operation	Algorithmic software device intended to automatically increase, decrease, and pause delivery of insulin based on iCGM readings and predicted glucose values	Identical
Communication and Pairing	Bluetooth Low Energy (BLE) wireless technology	Identical
Compatible Host Device	ACE Pump	Identical
Digitally Connected Devices	Cleared iCGM and ACE Pump, which includes a display device (Insulet-provided Controller phone or user's compatible smartphone)	Identical
System Functionality Modes	• iAGC enabled (Automated Mode): closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values • iAGC not enabled (Manual Mode): open loop, basal delivery based on user-defined programs	Identical
Alarms/Alerts	ACE Pump alarms/alerts will be displayed and communicated to the user via visual,	Identical

Element of Comparison	Subject Device: The Omnipod 6 algorithm	Predicate Device: The Omnipod 5 algorithm
	audible, and/or vibratory cues, as applicable.	
Target Glucose Control Range	100-150 mg/dl, user-customizable	Identical
Adaptive rate	Automatically adjusted adaptive rate personalized to user insulin history and bolus behavior.	Adaptive rate that automatically adjusts to user's insulin history.
Mechanism of Software Update	Firmware over the Air	Identical
History Storage	Up to 90 days (user insulin history)	Identical
Labeling	Package labels, User Guide, Technical User Guide and Important Safety Information	Identical, except for device name change (from Omnipod 5 algorithm to Omnipod 6 algorithm)

4. Summary of Clinical and Non-Clinical Performance Testing

Insulet conducted appropriate testing to confirm the Omnipod 6 algorithm meets all applicable iAGC Special Controls requirements defined in 21 CFR 862.1356 and supports the safety and effectiveness of the device as intended. Summaries of both clinical and non-clinical performance testing are provided below.

4.1 Summary of Clinical Performance Testing

Insulet conducted a pivotal study, "STRIVE" to evaluate the safety and efficacy of the Omnipod 6 algorithm. STRIVE was a randomized crossover study comparing the Omnipod 6 System (with Omnipod 6 algorithm) to the Omnipod 5 System (with Omnipod 5 algorithm) in 132 participants, including 98 participants with type 1 diabetes (ages 2 to 70 years) and 34 participants with type 2 diabetes (ages 18 to 70 years).

The participants started the study using either Omnipod 6 System or Omnipod 5 System for 4 weeks (Period 1) then switched to the opposite system for the next 4 weeks (Period 2) at the system's lowest available target glucose. Then, all participants used the Omnipod 6 System in an

extension phase for 4-6 weeks at a target glucose of 100 mg/dL with optional bolusing at a goal of no more than 3 boluses per day to induce reduction in manual boluses.

In the crossover study, the Omnipod 6 System met all primary safety endpoints, demonstrating non-inferiority to the Omnipod 5 System for percentage of time below 54 mg/dL, percentage of time below 70 mg/dL, percentage of time in range 70–180 mg/dL, and mean sensor glucose. There were no reports of severe hypoglycemia, diabetic ketoacidosis, or hyperosmolar hyperglycemic state, and no deaths, unanticipated adverse device effects, serious adverse device effects, or serious adverse events.

In addition, during the Crossover study, exploratory endpoints demonstrated improved glycemic metrics in the Omnipod 6 System group as compared to the Omnipod 5 System group including the percent of time in range 70 – 180 mg/dL, percentage of time in tight range 70 – 140 mg/dL, mean sensor glucose, percentage of time above 180 mg/dL, percentage of time above 250 mg/dL and percentage of time above 300 mg/dL.

During the optional bolus phase, participants used the Omnipod 6 System aiming for no more than three insulin boluses per day, to evaluate the ability of the algorithm to adapt and deliver increased insulin through automation. Two non-inferiority safety endpoints were evaluated against the Omnipod 5 System treatment group (crossover study): percentage of time below 54 mg/dL and percentage of time below 70 mg/dL. The results demonstrated that the Omnipod 6 System group during the optional bolus phase was non-inferior to the Omnipod 5 System group from the crossover study for hypoglycemia despite more insulin being delivered by the algorithm. Additionally, the difference between percentage of time in range 70-180 mg/dL during the optional bolus phase versus the Omnipod 5 System treatment group was not clinically meaningful even with nearly 50% fewer manual boluses being delivered and time in tight range of 70 to 140 mg/dL (a measure of time in normoglycemia) favored Omnipod 6 with reduced boluses. There were no reports of severe hypoglycemia (SH), diabetic ketoacidosis (DKA), or hyperosmolar hyperglycemic syndrome (HHS), and no deaths, unanticipated adverse device effects, serious adverse device effects, or serious adverse events occurred during the optional bolus phase.

4.2 Summary of Non-clinical Performance Testing

Software Verification and Validation:

Software Verification and Validation activities were performed in accordance with IEC 62304, FDA's guidance "*General Principles of Software Validation*" (issued January 2002). Software

documentation was provided in accordance with FDA guidance "*Content of Premarket Submissions for Device Software Functions*" (issued June 2023)

Interoperability:

Interoperability documentation is provided in accordance with 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 2017); demonstrates safe and effective operation of connected components and data exchange between system elements.

Usability/Human Factors:

No new Usability/Human Factors testing was performed to support this pre-market notification.

Labeling:

Insulet's user guides for the Omnipod 6 System, containing the Omnipod 6 algorithm includes a summary of the clinical trial. The labeling and training provided is sufficient for users and healthcare practitioners and satisfies applicable requirements of 21 CFR 801.

Risk Management

Risk Management was completed in accordance with ISO 14971. Verification activities, as required by the risk analysis, demonstrated that the acceptance criteria were met and the device is safe for use. All risks have been reduced as far as possible. The benefit risk analysis has determined that the benefits of using the device outweigh the residual risk, and the overall residual risk is acceptable.

5. Conclusion

The subject device (Omnipod 6 algorithm) has the same intended use and indications for use as the predicate device (Omnipod 5 algorithm). The Omnipod 6 algorithm has the same principles of operation and similar technological characteristics as the predicate device. There are some differences in the features and functionality between the subject and predicate devices, specifically the modification to adaptive rate to account for the user's personalized bolus behavior; but these differences do not raise different questions of safety and effectiveness. The required non-clinical and clinical performance data, provided in this Traditional 510(k) demonstrate that the subject device is as safe and as effective as the predicate device. Therefore,

Insulet concludes that the Omnipod 6 algorithm is substantially equivalent to its predicate, the Omnipod 5 algorithm.