August 26, 2024

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

Re: K241777
Trade/Device Name: SmartAdjust™ Technology
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJI
Dated: June 20, 2024
Received: June 20, 2024

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.

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

k241777

Device Name

SmartAdjust™ Technology

Indications for Use *(Describe)*

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 of age and older. SmartAdjust™ technology is intended for single patient 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

510(k) SUMMARY

Date prepared:	August 21, 2024
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
Secondary Contact Person **Phone:** **Fax:**	Lavanya Ramnath Senior Regulatory Affairs Specialist 213-326-6706 978-600-0120
Device Trade / Proprietary Name:	SmartAdjust™ technology
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:	K232741 (SmartAdjust™ technology)

Intended Use and Indications for Use

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 of age and older. SmartAdjust™ technology is intended for single patient use and requires a prescription.

Device Description

SmartAdjust™ technology 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.

SmartAdjust™ technology 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 SmartAdjust™ technology. SmartAdjust™ technology is intended to be digitally connected to a third party iCGM, the Omnipod 5 ACE Pump, and the SmartBolus Calculator.

The SmartAdjust™ technology software is installed on both the Omnipod 5 Pod and Omnipod 5 Controller (which contains the Omnipod 5 App), the 2 physical components that make up the Omnipod 5 System.

The Omnipod 5 System is a hybrid closed loop system and therefore can operate in either open loop (Manual Mode; SmartAdjust™ technology disabled) or closed loop (Automated Mode; SmartAdjust™ technology enabled). When Automated Mode is turned on, the SmartAdjust™ algorithm (installed on the Pod) controls insulin delivery based on recent CGM values.

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.

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Table 1: SmartAdjust™ technology Substantial Equivalence Comparison

Element of Comparison	Subject Device: SmartAdjust™ technology	Predicate Device: SmartAdjust™ technology (K232741)
Intended use/indications for use	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	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. 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®
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 ofinsulin based on iCGM readings and predicted glucose values
Communication and Pairing	Bluetooth Low Energy (BLE) wireless technology	Bluetooth Low Energy (BLE) wireless technology

Element of Comparison	Subject Device: SmartAdjust™ technology	Predicate Device: SmartAdjust™ technology (K232741)
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	• SmartAdjust™ technology enabled (Automated Mode): closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values • SmartAdjust™ technology not enabled (Manual Mode): open loop, basal delivery based on user-defined programs	• SmartAdjust™ technology enabled (Automated Mode): closed-loop, automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values • SmartAdjust™ technology not enabled (Manual Mode): open loop, basal delivery based on user-defined programs
Alarms/Alerts	• Out of Range Alert • Low Alert • Maximum Insulin/Delivery Alert	• Out of Range Alert • Low Alert • 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 Control Range	110-150 mg/dl, user-customizable	110-150 mg/dl, user-customizable
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

Summary of Non-Clinical Performance Testing

Human Factors Validation: Insulet performed a comprehensive Human Factors process that followed and complied with the FDA-recognized standards IEC 62366-1 and HE75 as well as FDA's guidance documents *Applying Human Factors and Usability Engineering to Medical Devices* – issued February 3, 2016, and *Content of Human Factors Information in Medical Device Marketing Submissions* – draft issued December 9, 2022. The validation study evaluated behavioral tasks and knowledge tasks with 16 representative study participants. The results of the validation test support the conclusion that SmartAdjust technology (as part of the Omnipod 5 System) is safe and effective for the intended users with type 2 diabetes, uses, and use environments.

Special Controls: Evaluation of the Special Controls for this device (regulation 21 CFR 862.1356) assures the safety and effectiveness of the device.

Summary of Clinical Performance Testing

Insulet performed a clinical study to validate the design of the SmartAdjust algorithm in people 18 years of age and older with type 2 diabetes. The study enrolled 343 participants diagnosed with type 2 diabetes. The primary safety endpoint was the change in HbA1c (noninferiority margin 0.3%) as measured by comparing participant values at baseline to the end of the study. The mean change in HbA1c was -0.8% ($P<0.001$ for non-inferiority). No safety concerns associated with the use of the device were identified during the study and there were no unexpected or serious adverse device effects. There were no DKA events, no hospitalizations or emergency visits for severe hypoglycemic events, and no instances of hyperosmolar hyperglycemic syndrome reported during the study.

Conclusion

SmartAdjust™ technology has the same intended use as the predicate device. The indications for use have been updated to add people 18 years and older with type 2 diabetes. Product labeling has been updated to include the expanded indication and clinical study results.

SmartAdjust™ technology has the same technological characteristics and principles of operation as the predicate device. There have been no design or software modifications to the subject device in relation to the indication change.

The changes to SmartAdjust™ technology are supported by clinical study and human factors validation data that demonstrates that the devices are substantially equivalent.

The differences between the predicate and subject devices do not raise any different questions about safety and effectiveness, therefore, SmartAdjust™ technology is substantially equivalent to its predicate.