January 27, 2022

Insulet Corporation
Julie Perkins
Sr. Director, Quality Assurance & Regulatory Affairs
100 Nagog Park
Acton, MA 01720

Re: K203772
Trade/Device Name: Omnipod 5 SmartBolus Calculator
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QRX, NDC
Dated: September 7, 2021
Received: September 7, 2021

Dear Julie Perkins:

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)*
K203772

Device Name
Omnipod 5 SmartBolus Calculator

Indications for Use *(Describe)*
The Omnipod 5 SmartBolus Calculator is software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose reading (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value. The Omnipod 5 SmartBolus Calculator 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:**	Julie Perkins Sr. Director, Quality Assurance & Regulatory Affairs 978-600-7951 (Office) 978-600-0120
Device Trade/Proprietary Name:	Omnipod 5 SmartBolus Calculator
Device Common Name:	Insulin Therapy Adjustment Device
Review Panel(s):	Clinical Chemistry
Product Code(s):	QRX, NDC
Regulation Numbers:	21 CFR 862.1358, 21 CFR 868.1890
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	K201476, DreaMed Advisor Pro

Device Description:

The Omnipod 5 SmartBolus Calculator is a software device that is a component of the Omnipod 5 Automated Insulin Delivery System. The SmartBolus Calculator exists on the Omnipod 5 App portion of the Omnipod 5 ACE Pump and relies on the user interface of the App.

The Omnipod 5 SmartBolus Calculator receives input parameters and settings from the other components of the system and calculates a suggested bolus amount of insulin to correct an elevated glucose level (a correction bolus) and/or to cover carbohydrates from a meal (meal bolus). The Omnipod 5 SmartBolus Calculator allows users to have the option of populating the current estimated glucose value and trend, which is communicated by the connected iCGM. Users may also manually enter the estimated glucose value or a blood glucose (BG) reading from a blood glucose meter. In addition to glucose, the suggested bolus dose is calculated based on the following parameters: user-entered carbohydrates, rate of change of the sensor glucose (if using a CGM), correction factor, insulin to carbohydrate ratio, target glucose value, and insulin on board (IOB). Once the calculation is complete, the user has the option of delivering the suggested dose of insulin, modifying the amount, or canceling.

The Omnipod 5 SmartBolus Calculator can be used in the Omnipod 5 Automated Insulin Delivery System with both Manual Mode and Automated Mode. When the Omnipod 5 SmartBolus Calculator is used with manually-entered BG readings, it suggests a bolus dose based on the same calculations as the currently cleared Omnipod DASH Insulin Management System (K180045, most recently cleared in K192659).

Indications for Use:

The Omnipod 5 SmartBolus Calculator is software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value. The Omnipod 5 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

Summary of Technological Characteristics Compared to Predicate Device:

The subject device and predicate device have the same principle of operation (algorithmic software device). Namely, both devices gather and analyze glucose information from continuous glucose monitoring systems and blood glucose meters to make suggestions for insulin therapy. While the predicate device is a web-based application, the subject device is integrated within the Omnipod 5 App. The Omnipod 5 SmartBolus Calculator and the predicate device are both insulin therapy adjustment devices with similar indications for use. The subject and predicate devices differ with respect to their device outputs. The differences between predicate and subject device do not raise new questions about safety and effectiveness. Therefore, the Omnipod 5 SmartBolus Calculator is substantially equivalent to the predicate device.

Standards Compliance

The Omnipod 5 SmartBolus Calculator complies with the following standards as documented in the applicable documents provided in this 510(k) submission:

- IEC 62366:2015 – Medical Devices – Part 1: Application of Usability Engineering
- HE75:2009 – Human Factors Engineering – Design of Medical Devices
- 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
- ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good clinical practice

Summary of Non-Clinical Performance Data

The Omnipod 5 SmartBolus Calculator was designed and developed as part of the Omnipod 5 Automated Insulin Delivery System in accordance with Insulet procedures for Design Control, Software Development, and Risk Management. The information presented in this 510(k) demonstrate the safety and effectiveness of the Omnipod 5 SmartBolus Calculator. Performance testing with the Omnipod 5 SmartBolus Calculator as part of the Omnipod 5 App 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 devices are 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 SmartBolus Calculator with intended users in the expected use environments, including associated training and accompanying documentation. The results of the validation demonstrate that the SmartBolus Calculator 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.
- **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 SmartBolus Calculator 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.
- **Special Controls:** Evaluation of the Special Controls for this device (regulation 21 CFR 862.1358) assures the safety and effectiveness of the device.

Summary of Clinical Performance Data

A study was conducted on 25 participants with type 1 diabetes aged 6-70 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator. During Phase 1, participants used the Omnipod 5 System in Manual Mode for the first 7 days without a connected CGM (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 System in Manual Mode with a connected CGM (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/ or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current CGM value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the CGM trend.

The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by CGM between the two study phases. The results indicate that the use of the CGM-informed SmartBolus Calculator was associated with less time in hypoglycemia within 4 hours of bolusing.

Comparison of Glycemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (N=25)

Percent time in glucose range as measured by CGM	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70-180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 300 mg/dL	2.0% (2.6)	2.6% (3.7)	0.6%

Data is presented as average (standard deviation). Significant differences ($p<0.05$) are highlighted with an asterisk.

Substantial Equivalence Conclusion:

The Omnipod 5 SmartBolus Calculator has the same intended use and similar indications for use as the predicate device. The differences in indications for use and technological characteristics between the subject and predicate device do not raise new questions of safety and effectiveness. Through robust performance testing, including a clinical study, the predicate device has been shown to meet the Insulin Therapy Adjustment Device special controls and to be safe and effective. Therefore, the Omnipod 5 SmartBolus Calculator is substantially equivalent to its predicate device.