August 19, 2022

Insulet Corporation
Alexander Hamad
Sr. Regulatory Affairs Specialist
100 Nagog Park
Acton, MA 01720

Re: K222239
Trade/Device Name: SmartBolus Calculator
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QRX, NDC
Dated: July 26, 2022
Received: July 26, 2022

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 (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,

Paula Caposino, Ph.D.
Acting Deputy Director
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)*
K222239

Device Name
SmartBolus Calculator

Indications for Use *(Describe)*
The SmartBolus Calculator is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The 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 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

K222239 – 510(K) SUMMARY

Date Prepared:	August 19, 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:**	Alexander Hamad Sr. Regulatory Affairs Specialist 978-600-2432 978-600-0120
Device Trade/Proprietary Name:	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
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	K203772 (SmartBolus Calculator)

5.1 Purpose of Submission

The purpose of this submission is to modify the legally marketed SmartBolus Calculator to expand the age range in the devices' indications for use from 6 years and older to 2 years and older.

5.2 Device Description

The 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 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 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 SmartBolus Calculator can be used in the Omnipod 5 Automated Insulin Delivery System with both Manual Mode and Automated Mode.

5.3 Summary of Technological Characteristics Compared to Predicate Device

The technological characteristics of the subject device are identical to the predicate device cleared in K203772. There have been no modifications to the design or software of the device.

There are no changes to the device's intended use, however, the indications for use is being modified to lower the age range from 6 years and older to 2 years and older.

5.4 Indications for Use:

The table below provides the indications for use for the SmartBolus Calculator subject device as compared to the predicate.

Table 5.01: SmartBolus Calculator Substantial Equivalence Comparison

Element of Comparison	Subject Device: SmartBolus Calculator	Predicate Device: SmartBolus Calculator (K203772)	Comparison
Indications for Use	The SmartBolus Calculator is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The 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 SmartBolus Calculator is intended for single patient, home use and requires a prescription.	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.	Same, except for the age indication (minimum age lowered from 6 to 2)
Age Range of Intended Users	Persons aged 2 and older	Persons aged 6 and older	Difference in age indication (proposed change per this 510k submission)

5.5 Standards Compliance

The SmartBolus Calculator complies with the following standards in relation to the proposed change within this submission:

- ANSI AAMI IEC 62366-1:2015 – Medical Devices – Part 1: Application of Usability Engineering
- ANSI AAMI HE75:2009/(R)2018 – Human Factors Engineering – Design of Medical Devices
- ANSI AAMI ISO 14971:2019 – Medical devices – Application of Risk Management

to Medical Devices

- ANSI AAMI ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good clinical practice

5.6 Non-Clinical Performance Data

To demonstrate the safety and effectiveness of the commercial Omnipod 5 Automated Insulin Delivery System user interface, Insulet executed a comprehensive Human Factors formative and validation testing process that followed and complied with the FDA recognized standards 62366-1 and HE75. This process is in-line with the Agency's current thinking regarding iterative design and Human Factors testing methodologies as described in their most recent guidance: Applying Human Factors and Usability Engineering to Medical Devices. The validation test was simulated and structured to mimic actual use, utilized an equivalent to production version of the system, and was designed to be sufficiently sensitive to capture use related problems, if they existed. The study was conducted to ensure sufficient data collection for the "Caregivers of Children with Diabetes" user group, with specific focus on caregivers of young children (aged 2-5.9 years). In total, 16 participants were included in the study.

The Omnipod 5 System has been found to be substantially equivalent to the predicate for the intended users, uses, and use environments. Any additional modifications to the user interface related to the safety critical tasks (including the device, training, and labeling) would not further reduce risk, are not possible or not practical, and the remaining residual use-related risks are outweighed by the benefits derived from use of the device.

5.7 Clinical Performance Data

The following clinical data were provided in support of the substantial equivalence determination for the expansion of the indications for use for the SmartBolus Calculator. These data supplement the existing performance data presented in the 510(k) submissions for the predicate device (K203772).

A clinical study was performed on the SmartBolus Calculator within the Omnipod 5 System per ISO 14155:2011 with the objective to assess the safety and effectiveness of the device for use in patients aged 2.0-5.9 years with type 1 diabetes during Manual Mode operation.

This single-arm, multi-center, prospective clinical study enrolled 5 subjects across 2 US clinical sites. The study used the Omnipod 5 System in Manual Mode and consisted of two outpatient phases - 7 days of Omnipod 5 System use in Manual Mode without a connected CGM using manual entry of BG values to deliver boluses (Phase 1), followed by 7 days of Omnipod 5 System use in Manual Mode with a connected CGM using the SmartBolus Calculator to deliver boluses (Phase 2).

The primary objective of this study was to evaluate the safety of the SmartBolus Calculator using glucose metrics of percentage of time < 70 mg/dL and percentage of time > 180 mg/dL during the 4-hour post bolus period from Phase 1 as compared to Phase 2. The mean percentage of time blood glucose levels were < 70 mg/dL for the preschool cohort (aged 2.0 to 5.9 years) from Phase 1 was 5.16% as compared to 4.03% in Phase 2 resulting in non-statistically significant decrease of 1.13% (P = 0.6250). The mean percentage of time blood glucose levels were > 180 mg/dL for the preschool cohort from Phase 1 was 35.2% as compared to 33.2% in Phase 2, a decrease of 2.03% that was not statistically significant (P = 1.0000).

In the 5 subjects enrolled in the preschool cohort of 2.0-5.9 years, there were zero (0) deaths, zero (0) serious adverse events, and zero (0) unanticipated adverse device effects (UADE) reported. There was one (1) non-serious adverse event reported (prolonged hyperglycemia).

In summary, the results of this study indicate the SmartBolus Calculator is substantially equivalent to the predicate and performed as expected when used to deliver boluses in Manual Mode by entering a manual reading or using the CGM value in the bolus calculator, during both the day and night, in preschool subjects aged 2.0-5.9 years with type 1 diabetes. Results demonstrated similar glucose metrics with the use of the SmartBolus Calculator (Phase 2) as compared to manual entry of blood glucose values for the delivery of boluses (Phase 1) for the preschool cohort. No safety concerns were reported during the study.

5.8 Substantial Equivalence Conclusion

The subject device, the SmartBolus Calculator, has the same intended use and similar indications for use as the predicate device. There are no technological differences between the subject and predicate device, only a difference in the age range within the indications for

use. The difference in indications for use between the subject and predicate device do not raise new questions of safety and effectiveness. Clinical validation successfully demonstrates that the SmartBolus Calculator has been found to be substantially equivalent to the predicate for the intended users, uses, and use environments. Therefore, the SmartBolus Calculator is substantially equivalent to the predicate device.