



October 18, 2023

Insulet Corporation
Maria Brower
Senior Specialist Regulatory Affairs
100 Nagog Park
Acton, MA 01720

Re: K231824
Trade/Device Name: SmartBolus Calculator
Regulation Number: 21 CFR 862.1358
Regulation Name: Insulin Therapy Adjustment Device
Regulatory Class: Class II
Product Code: QRX
Dated: September 19, 2023
Received: September 19, 2023

Dear Maria Brower:

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 Toxicology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K231824

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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K231824 510(K) SUMMARY

Date prepared:	October 16, 2023
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:	Maria Brower, Senior Specialist, Regulatory Affairs, Digital Health 978-600-7000
Secondary Contact Person Phone: Fax:	Katie Pacheco, Director Regulatory Affairs, Digital Health 978-600-7000 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:	K222239 (SmartBolus Calculator)

5.1 Purpose of Submission

The SmartBolus Calculator is being modified to be compatible with the iOS version of the Omnipod 5 App component of the Omnipod 5 ACE Pump.

5.2 Intended 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.

5.3 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 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 sensors 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.

5.4 Summary of Technological Characteristics Compared to Predicate Device

There is no change to the SmartBolus Calculator that is compatible with the Android version of the Omnipod 5 App. In addition, the SmartBolus Calculator calculations and data inputs are identical to the predicate (K222239). The Subject device (SmartBolus Calculator hosted within the Omnipod 5 App (iOS)) is written in an iOS compatible programming language. The different programming language does not raise different questions about safety and effectiveness because both software items implement the exact same fundamental calculation with no difference in glucose input parameters or calculation.

The differences between predicate and subject device do not raise any different questions about safety and effectiveness, and performance data demonstrates the Omnipod 5 ACE Pump is substantially equivalent to its predicate. **Table 5.01** below illustrates the equivalence of the subject device to the predicate.

The user interface for the SmartBolus Calculator is regulated as part of the Omnipod 5 ACE Pump (Omnipod 5 App component) and therefore UI changes are described the concurrent 510(k) submission for the Omnipod 5 ACE Pump.

Table 5-01. SmartBolus Calculator Substantial Equivalence Comparison

Element of Comparison	Subject Device: SmartBolus Calculator	Predicate Device: SmartBolus Calculator (K222239)
Intended use/ 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 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.
Age Range of Intended Users	Persons aged 2 and older	Persons aged 2 and older
Device Outputs and Insulin Therapy Adjustment Recommendations Type	The SmartBolus Calculator calculates a suggested bolus dose output to the ACE Pump and also calculates the insulin-on-board.	The SmartBolus Calculator calculates a suggested bolus dose output to the iAGC and also calculates the insulin-on-board.
Principles of Operation	Algorithmic software device	Algorithmic software device
Programming Language	Android and iOS compatible programming language	Android compatible programming language

5.5 Standards Compliance

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

Standard	Title	FDA Recognition No.
ANSI AAMI ISO 14971:2019	Medical devices – Application of Risk Management to Medical Devices	5-125
IEC 62304:2015-06	Medical Devices Software - (Software life cycle processes)	13-79

5.6 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 was focused primarily on software verification and validation for the SmartBolus Calculator. Human factors validation for the SmartBolus Calculator was done as part of the Omnipod 5 ACE Pump validation (provided in K231826). There was no impact to clinical performance of the SmartBolus Calculator for the design change discussed in this submission.

Performance testing for the addition of an iOS compatible SmartBolus Calculator included the following:

- Risk Management: risk management was completed in accordance with ISO 14971:2019. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the device is safe for use.
- Software Validation: software verification and validation testing were 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 *Content of Premarket Submissions for Device Software Functions* - Issued June 2023.

- Special Controls: evaluation of the Special Controls for this device (regulation 21 CFR 862.1358) supports the safety and effectiveness of the device.

5.7 Substantial Equivalence Conclusion

The SmartBolus Calculator has the same intended use and indications for use as the predicate device. The difference in technological characteristics (software programming language) of the subject device compared to the predicate device does not raise different questions of safety and effectiveness. Through performance testing, the Subject device has been shown to meet the Special Controls and determined to be substantially equivalent to its predicate.