



Food and Drug Administration
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April 18, 2017

Insulet Corporation
Matthew King
Director, Regulatory Affairs and Design Quality Assurance
600 Technology Park Drive Suite 200
Billerica, MA 01821 US

Re: K162296
Trade/Device Name: OmniPod Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG, NBW, NDC
Dated: February 28, 2017
Received: March 1, 2017

Dear Matthew King:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

 Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K162296

Device Name
OmniPod Insulin Management System

Indications for Use (Describe)

The OmniPod Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott FreeStyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary Complying with 21 CFR 807.92

Date prepared: February 23, 2017

Submitter Name: Insulet Corporation

Submitter Address: 600 Technology Park Drive, Suite 200
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FDA Establishment Registration Number: 3004464228

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FDA Establishment Registration Number 3307710663

Device Trade / Proprietary Name: OmniPod Insulin Management System

Device Common Name: Pump, Infusion, Insulin

Regulation Description: Infusion pump

Regulation Medical Specialty: General Hospital

Review Panel: General Hospital

Product Code: LZG (Pump, Infusion, Insulin)
NBW (System, Test, Blood Glucose, Over The Counter)
NDC (Calculator, Drug Dose)

Submission Type: Traditional 510(k)

Regulation Number: 21 CFR 880.5725 Infusion Pump

Device Class: 2

Model number (Pod/10-pack): ZXP425

Model number (PDM): 14500-5A (UST400)

Device predicate: K122953 OmniPod Insulin Management System

Purpose of Submission:

Modification to a legally marketed device to address product improvement and design updates.

Device Description:

The proposed device provides for the management of insulin therapy and blood glucose monitoring by patients with diabetes mellitus. It is comprised of two primary components: the disposable insulin infusion pump (Pod) and an associated wireless remote controller referred to as the Personal Diabetes Manager (PDM) with an embedded blood glucose meter. The PDM incorporates a suggested bolus calculator which aids the user in determining the insulin bolus dosage needed based on carbohydrates ingested, most recent blood glucose reading, programmable correction factor, insulin to carbohydrate ratio, target blood glucose value and Insulin on Board (IOB).

Indications for Use:

The OmniPod[®] Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle[®] test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

The subject device has identical intended use and indications for use as the predicate.

Summary of Technological Characteristics Compared to Predicate Device

The subject device has the same principle of operation as the predicate device. This submission includes 26 modifications to the hardware, materials in contact with the body and fluid path, packaging and sterilization, manufacturing process, and software as compared to the predicate. These changes include:

Hardware: replacement of PDM backup batteries with a charge capacitor for better reliability, tolerance relief on a component in the needle mechanism, changes to the Pod top housing and adding a needle bend to alleviate buckling at manufacturing, plunger tolerance changes for more rapid cycling in manufacturing, an updated ASIC for the Pod, spring latch tolerance changes for better performance, increasing a dimension on the top housing to contend with a tolerance stack-up, addition of a bend to the piezo spring to prevent spring fallout at final test, and tolerance changes to the device kill switch.

Materials: Introduction of a new insulin transfer syringe, addition of a second supplier for cannula tubing, and a change to the cyclopy resin covering of the PDM.

Packaging: Introduction of a new automated packaging machine, addition of a new vendor for sterilization, and new tray and lid stock for the automated packaging machine.

Process: Addition of a new vendor to convert Pod adhesive, and a new specification for the SMA wire symmetry for better performance.

Software: Updates to the OmniPod PDM main processor software, updates to the occlusion alarm software, and updates to the OmniPod Pod software.

Performance Data and Standards Compliance:

Insulet completed the appropriate validation and verification activities recommended by the *Guidance for Industry and FDA Staff- Total Product Life Cycle: Infusion Pump- Premarket Notification [501(k)] Submissions Guidance* and other guidance, as applicable. The following performance testing has confirmed the OmniPod[®] Insulin Management System to be substantially equivalent to the predicate device.

- **Safety Assurance Case;** an assurance case was provided for the OmniPod[®] Insulin Management System as recommended in the FDA Guidance: Infusion Pumps Total Product Life Cycle. The stated goal of the safety assurance case is:
 - The OmniPod[®] Insulin Management System with blood glucose monitor and dose calculator is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis.

The three high level arguments in the safety assurance case are:

- The OmniPod Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and has been adequately evaluated for risk mitigations arising from identified hazards.
- The OmniPod Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and has been adequately designed to function for the intended use and the intended period of use defined for the device.
- The OmniPod Insulin Management System is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis, and the design specifications have been adequately verified and validated.

The supporting evidence demonstrates that the following general categories of hazards have been adequately addressed:

- Infusion delivery errors
 - Incorrect set up of the PDM leading to over-infusion, under-infusion or delay in infusion of insulin
 - Incorrect entry of insulin prescription leading to overdose or underdose (due to error, incorrect key strokes, accidentally pressing wrong key, confusion, inadvertently pushing buttons)

- User workaround or bypassing of software limits on insulin dose parameters leading to overdose or underdose of insulin
- User error in insulin infusion during pump activation due to misunderstanding of pump operation, leading to overdose or underdose of insulin
- User error in insulin infusion during pump activation due to inputting incorrect insulin values, leading to overdose or underdose of insulin
- User activates incorrect Pod leading to over-infusion or under-infusion of insulin
- Accidental use of another user's PDM after Pod activation, leading to over- or under-infusion of insulin
- EMC or EMI interference causing device malfunction, leading to over-delivery or under-delivery of insulin
- Battery disconnection or component damage resulting in surge caused by dropping of PDM, leading to over-delivery or under-delivery of insulin
- Electronic component damage caused by shipping of PDM, leading to incorrect signal to the Pod resulting in over-delivery or under-delivery of insulin
- PDM exposed to water causing a short, resulting in incorrect signals to Pod, leading to over-delivery or under-delivery
- PDM screen cracks preventing user from adequately programming bolus, leading to over-delivery or under-delivery
- User receives incorrect blood glucose readings from integrated BG meter, resulting in over-infusion or under-infusion of insulin
- User receives over-infusion of insulin due stuck PDM keys giving a continual bolus delivery signal to the Pod
- PDM software algorithm error results in errant insulin infusion program on the Pod causing over-infusion or under-infusion of insulin
- Device is occluded and insulin flow into subcutaneous tissue is restricted leading to hyperglycemia
- Flow from Pod is higher than expected during the basal program or a bolus resulting in over-infusion of insulin
- PDM loses backup power and loses the date and time, resulting in a Pod being rendered unusable, leading to an unanticipated delay in insulin infusion and hyperglycemia.
- Pod encounters partial deploy/partial retraction of needle mechanism upon firing into subcutaneous tissue resulting in under-delivery and hyperglycemia.
- Pod encounters partial deploy, failed deploy, or partial retract due to lack of clearance between components of needle mechanism resulting in under-delivery of insulin and hyperglycemia.
- Pod encounters partial deploy, or partial retract due to interference of needle mechanism resulting in under-delivery of insulin and hyperglycemia.
- Plunger is changed and fails to operate as intended, leading to a defective Pod, leading to a delay in use which may lead to hyperglycemia.
- Pod software fails prior to, or during operation, stopping infusion and resulting in an alarm which could cause delay in treatment and hyperglycemia.
- Pod does not activate upon command, spring latch does not release drive mechanism, resulting in a failed Pod and hyperglycemia.
- Pod top housing loses structural integrity and all function is lost, resulting in delay in treatment and hyperglycemia.

- Pod has no audible alarm that user can hear resulting in a missed occlusion alarm, which could lead to hyperglycemia.
- Software Algorithm failure due to software updates to the device. Leads to users experiencing hyperglycemia. Software updates include:
 - Eliminate function of up/down buttons on “Welcome” screen; Abbreviate a not on the “BG Target/Correct above” confirmation screen; address bug causing pod error alarm during Pod-PDM communication.
 - Address display issues and formatting, and address stuck key alarms occurring without actual alarm condition.
 - Remove 73-78 hour expiration reminder alerts; corrected an unexpected PDM reset condition; prevented the background pod status check from overwriting an active pod communication.
 - Corrected timeout value for the Aux to complete communication; Disabled up/down buttons when viewing BG multiday trends.
 - Fix bug that caused the device to go into alarm while downloading engineering logs; modify basal program creation so that the default rate for the initial basal segment is 0.0U; changes to support new parts and replace obsolete parts.
 - Enable occlusion algorithm when the bolus was cancelled.
 - Updated occlusion noise filtering algorithm to reduce false occlusion alarms; Occlusion related alarms split into separate alarm codes to help with diagnosing issues; Updates to occlusion stall algorithm to catch missed stalls; Added occlusion disqualification rules 1& 2 to dismiss false occlusions that don’t have the proper pulse width occlusion signature.
 - Improvements to the occlusion stall algorithm; Added Occlusion Disqualification Rule; Average of last 10 pulses on both wires does not show a rise; Add 30 minute monitoring period. If a potential occlusion is detected, monitor the pulse widths for 30 minutes to determine if this is a real occlusion.
- User activates Pod and needle does not deploy leading to hyperglycemia.
- Pod needle does not achieve required depth and angle for adequate infusion, leading to hyperglycemia.
- User miscalculates the amount of carbs they have consumed, resulting in a bolus that is too high or too low to account for their insulin requirement. The user becomes hypoglycemic or hyperglycemic.
- The user selects a bolus that is greater than what is needed and experiences hypoglycemia.
- The user does not calculate their bolus correctly by not correcting their current BG from their target BG, and experience hyperglycemia.
- The user miscalculates their correction bolus by not taking insulin already present in their body (insulin on board) into account, and experience hypoglycemia.
- The user is not able to calculate a meal bolus and experiences hyperglycemia.
- The user is not able to calculate the insulin on board with a meal bolus and experiences hypoglycemia
- The user experiences an occlusion at the time of a bolus delivery. When the occlusion clears, the bolus is delivered and the user experiences hypoglycemia (post occlusion bolus).
- Incorrect therapy or treatment
- Biological or chemical contamination

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- Insulin potency impacted by material leaching out of the fluid path materials, leading to chemical contamination, hypoglycemia, or hyperglycemia
- Insulin sterility not maintained over the Pod wear period, resulting in infection
- Body contacting parts of System cause biocompatibility issues to the user's skin and other bodily tissues, resulting in inconvenience to serious injury
- Insulin fill syringe manufactured with materials that leach through subcutaneous tissue and patient experiences toxic response and is injured.
- Fluid path manufactured with materials that leach through subcutaneous tissue and patient experiences toxic response and is injured.
- The PDM outer casing is exposed to pathogens or other infectious substances that cannot be appropriately disinfected or cleaned. This leads to the user experiencing an infection.
- The Pod sterile packaging is changed from its original sterile-validated state, compromising the sterile barrier of the packaging. This leads to the user experiencing infection.
- Traumatic injury
 - User receives electrical shock from PDM
 - User receives electrical shock from Pod
- **Risk Management;** was completed in accordance with ISO 14971:2007- *Medical Devices- Application of Risk Management to Medical Devices*. Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the device is free from unacceptable risk.
- **Soft Cannula Depth and Angle Studies;** testing was conducted to verify that the soft cannula insertion depth and angle of the Pod meets the specification. All Pod samples tested met the requirements.
- **Biocompatibility;** this submission includes verification testing per ISO 10993, Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 6: Tests for local effects after implantation, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation and skin sensitization, and Part 11: Tests for systemic toxicity, and ASTM F756 Standard Practice for Assessment of Hemolytic Properties of Materials.
- The following performance tests were conducted on the subject device to demonstrate the subject device meets the same essential performance specifications as the predicate:
 - Bolus and Basal Flow Accuracy
 - Basal (continuous) Flow
 - Bolus Flow
 - Occlusion Bolus
 - Alarms for pod expiration, empty reservoir, and occlusion

The OmniPod[®] Insulin Management System complies with the following standards as documented in the applicable test reports provided in this 510(k) submission. The OmniPod[®] Insulin Management System has had its design considered in accordance with the

Guidance for Industry and FDA Staff: Infusion Pumps Total Product Life Cycle, released December 2, 2014. Verification and validation reports demonstrate that the OmniPod[®] Insulin Management System meets its intended use and design requirements.

ISO 10993-1 (2009) Fourth Edition Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process

ISO 10993-3:2014 Biological Evaluation of Medical Devices- Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for *in Vitro* Cytotoxicity

ISO 10993-6:2007 Biological Evaluation of Medical Devices- Part 6: Test for Local Effects After Implantation

ISO 10993-7:2008 Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals

ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization

ISO 10993-11:2006 Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity

ISO 14971 Second Edition 2007-03-01 Medical Devices- Application of Risk Management to Medical Devices

IEC 60601-1:2005 Ed.3+A1:C1:2014 Medical Electrical Equipment- Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2 Ed. 4.0 b: 2014 Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Disturbances- Requirements and Tests

IEC 60601-1-6 Ed. 3.1 b: 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-1-8 Ed. 2.1 b: 2012 Medical Electrical Equipment- Part 1-8: General Requirements for Basic Safety and Essential Performance- Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.

IEC 60601-1-11 Issued: 2015/01/20 Ed.2 Medical Electrical Equipment- Part 1-11: General Requirements for Basic Safety and Essential Performance- Collateral Standard- Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

IEC 60601-2-24 Ed. 2.0 b: 2012 Medical Electrical Equipment- Part 2-24:
Particular Requirements for the Basic Safety and Essential Performance Infusion
Pumps and Controllers

IEC 62366 Ed. 1.1 b. 2014 Medical Devices - Application of Usability Engineering To
Medical Devices

Substantial Equivalence Conclusion:

The modified OmniPod[®] Insulin Management System has the same indications for use and principle of operation as the device cleared as K122953. Modifications have been made to the predicate device in the following categories: hardware, software, process, materials, and packaging. The proposed modifications do not affect the intended use of the predicate device. The changes to the technological characteristics did not raise new questions of safety and effectiveness. Performance bench testing and comparison to the predicate demonstrated that the subject device met all device specifications and is substantially equivalent to the predicate device.