DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2016

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

Re: K160252
Trade/Device Name: Omnipod Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, NBW
Dated: January 30, 2016
Received: February 1, 2016

Dear Mr. 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" (21 CFR 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 yours,


for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160252

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)*

Insulet Corporation

# 510(k) Summary Complying with 21 CFR 807.92

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|---|---|
| **510(k)** | K160252 |
| **Date prepared:** | April 26, 2016 |
| **Submitter Name:** | Insulet Corporation |
| **Submitter Address:** | 600 Technology Park Drive, Suite 200<br>Billerica, MA 01821 |
| **FDA Establishment Owner/Operator Number:** | 9056196 |
| **FDA Establishment Registration Number:** | 3004464228 |
| **Contact Person:** | Matthew King<br>Director of Regulatory Affairs and Design Quality Assurance |
| **Phone:** | (978) 600-7427 (office)<br>(603)459-9755 (mobile) |
| **Fax:** | (978) 600-0120 |
| **Manufacturing Site:** | Flextronics Industrial (Shenzhen) Co., LTD.<br>Building 2-3, Yusheng Industrial Park, 467 Xixiang Section<br>National Highway 107, Xixiang, Baoan District<br>Shenzhen Guangdong, 518126, China<br>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<br>NBW |
| **Submission Type:** | Traditional 510(k) Corrective Actions Being Effected |
| **Regulation Number:** | 21 CFR 880.5725 |
| **Device Class:** | 2 |
| **Model number (Pod/10-pack):** | ZXP425 |
| **Model number (PDM):** | 14500-5A (UST400) |
| **Device predicate:** | K122953 OmniPod® Insulin Management System |

**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.

**Indications for use:**

The following Indications for Use are identical to the predicate device:

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.

**Technological Characteristics:**

The technological characteristics, design, material composition, energy source, principal of operation, and configuration of the OmniPod® Insulin Management System are not changed from those cleared in K122953 as a result of the modifications described in this pre-market notification.

**Summary of Device Modifications**

The following three device modifications were submitted in accordance with K95-1 Memorandum "510(k) Requirements for Proposes Fixes for Devices Undergoing Recall."

1. Modify the component responsible for preventing the cannula from retracting after insertion into the skin tissue (e.g., remove catch wings from the insertion mechanism and replace them with a catch beam).
2. Modify the dimensions of the insertion mechanism release bar to improve performance.
3. Add medical grade silicone lubricant to the modified release bar to improve performance and correct an issue found through an increase in needle mechanism field complaints.

The three modifications were made to address the needle deployment mechanism recall Z-0393-2016 and Z-0394-2016. These modifications are described in detail, analyzed for their risk, and results of verification testing are summarized in this submission. The sum of these changes do not raise different questions of safety or effectiveness of the OmniPod® Insulin Management System.

**Performance Data**

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 [510(k)] Submissions Guidance* and other guidance, as applicable. The following performance testing has confirmed the OmniPod Insulin Management System to be substantial equivalent to the predicate device.

- **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 safe for use.
- **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.
- **Cam finger;** the cam finger design has been verified to perform as defined by its requirements.
- **Insertion mechanism release;** testing was conducted to demonstrate that the Release Bar meets its design intent and releases the insertion mechanism. Testing confirmed that design intent was met and the Release Bar is capable of releasing the insertion mechanism.
- **Cannula insertion retention;** testing was conducted to demonstrate that the Catch Beam meets its design intent and retains the Soft Cannula at the specified depth. Testing confirmed that design intent was met and the Catch Beam is capable of retaining the Soft Cannula at the specified depth.
- **Cannula insertion indicator;** an indicator has been provided and tested to confirm when the cannula is fully inserted.
- **Biocompatibility;** an assessment of the additional silicone lubricant has been completed which rationalizes the additional silicone for human use as acceptable. The added silicone is not in contact with the fluid path. The same silicone is cleared with the predicate device for use at the needle tip/ needle cap interface which is in the fluid path. The predicate submission includes verification testing per ISO 10993, Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity, Part 5: Tests for in vitro cytotoxicity, Part 6: Tests for local effects after implantation, and Part 10: Tests for irritation and skin sensitization.

**Substantial Equivalence Conclusion**

The modified OmniPod® Insulin Management System uses the same technology, indications for use, materials, and modes of operation as the device cleared as K122953. The proposed modifications do not affect the intended use or technological characteristics of the predicate device. Performance bench testing demonstrated that the subject device met all device specifications. Therefore, the subject device is substantially equivalent to the predicate device.