K122953

7.0 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

DEC 07 2012

A. Submitter's Information:

Date prepared:	September 24, 2012
Name:	Insulet Corporation
Address:	9 Oak Park Drive Bedford, MA 01730 United States
FDA Establishment Owner/Operator Number:	9056196
Contact Person:	Michael J. Doyle Director Regulatory & Clinical Affairs
Phone:	(781) 457-5244
Fax:	(781) 357-4303
Manufacturing Site:	Insulet Corporation 9 Oak Park Drive Bedford, MA 01730 United States
FDA Establishment Registration Number:	3004464228

B. Device Name:

Trade/Proprietary Name:	OmniPod Insulin Management System
Device:	Pump, Infusion, Insulin
Regulation Description:	Infusion pump
Regulation Medical Specialty:	General Hospital
Review Panel:	General Hospital
Product Code:	LZG NBW
Submission Type:	510(k)
Regulation Number:	880.5725 and 862.1345
Device Class:	2
Model number (Pod/10-pack):	ZXP425
Model number (PDM):	14500-5A (UST400 Series)
Device predicate:	K111669 – FreeStyle® Glucose Meter incorporated into the OmniPod Insulin Management Systems K042792 – iXL-II Diabetes Management System

C. Device Description/Indications for Use:

The OmniPod Insulin Management System 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 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.

D. Technological Characteristics:

The OmniPod Insulin Management System has the same technological characteristics and is similar in design and configuration as compared to the predicate device.

E. Summary of Non-Clinical Test/Performance Testing – Bench

Insulet completed the appropriate validation and verification activities required by the *Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions Draft Guidance* and other guidance, as applicable. The following performance and safety testing has confirmed the OmniPod Insulin Management System to be substantial equivalent to the predicate device;

- **Usability**; testing was conducted in accordance with the guidance provided in *IEC 62366:2007, Medical devices -- Application of usability engineering to medical devices, AAMI HE75 – Human Factors Engineering – Design of Medical Devices,* and the FDA's *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management Guidance.* Device usability has been fully validated.
- **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.
- **Fluid Path Integrity Design;** testing was conducted and verified that the fluid path within the Pod can withstand the required internal pressures.
- **Environmental Testing**; testing consisted of exposing PDMs to various environmental conditions: temperature, humidity, and pressure (atmospheric) per IEC 60601-2-24. The PDM's met the environmental testing requirements and passed all the required functional tests.

- **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.
- **Priming Volume;** testing was performed to verify appropriate insertion mechanism release and priming of cannula after firing of needle. The Pod met the priming volume requirements after soft cannula deployment as part of the activation sequence.
- **Rotational Sensor Study**; testing was conducted to demonstrate that the rotational sensor meets its design intent and maintains required electrical contact. Testing confirmed that design intent was met and the rotational sensor is capable of making and maintaining electrical contact in all installed positions.
- **Reliability and Useful Life;** testing was conducted to verify the mechanical and functional integrity of the common use features of the PDM and ensure that the useful (labeled warranty) life requirement is achieved. Testing verified that the PDM met the reliability and useful life requirements.
- **Basal Flow Accuracy;** testing was performed to confirm the accuracy of basal rate delivery per IEC 60601-2-24. Verification indicated that an accuracy of +/- 5% at rates of 0.05 U/hr – 30.00 U/hr was met.
- **Bolus Flow Accuracy;** testing was performed to verify bolus delivery accuracy per IEC 60601-2-24, Pods were tested and confirmed to provide a bolus accuracy of +/- 5% for all set values of 0.05 – 30.00 units.
- **Basal accuracy at maximum and minimum operational temperature**; testing of the Pod passed the basal flow rates at the minimum and maximum operational temperatures.
- **Nominal flow basal with vacuum transition at nominal temperature;** the proposed Pod was developed and confirmed to provide a nominal flow basal with vacuum transition at nominal temperature, as defined.
- **Power interruptions**; the proposed Pod battery connections were tested and determined to be perform as intended.
- **Cam finger;** the cam finger design has been verified to perform as defined by its requirements.
- **Cannula insertion indicator;** an indicator has been provided and tested to confirm when the cannula is fully inserted.
- **Pod temperature testing;** the Pod has been tested and confirmed to operate at a temperature range of 40°F to 98.6°F.
- **Biocompatibility;** an assessment of the OmniPod Insulin Management System was performed consistent with *FDA's Blue Book Memorandum G95-1 "Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* on the fluid extracts of the Pod fluid path components (Surface device, breached or compromised, permanent wear) and the surface pad and adhesive (Surface device, skin contact, permanent wear) of the Pod base. These body contacting components were tested under GLP controlled conditions. The results of the testing showed that the fluid path and Pod base adhesive pose no concerns for human use due to problems associated with biocompatibility, toxicity or dermal sensitization.

- **Insulin compatibility**; the OmniPod Insulin Management System has been tested and is considered to be compatible with NovoLog®, HumaLog®, and Apidra® U-100 insulin.
- **Sterilization**; the proposed device (Pod) and disposable set have been tested and will be sterilized by 100% ethylene oxide.
- **Software**; documentation was prepared and submitted for a MAJOR level of concern device in accordance with *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical devices*.
- **Electrical safety**; the OmniPod Insulin Management System has been tested and successfully passed all of the relevant sections of IEC 60601-1 Medical electrical equipment, General requirements for Safety.
- **RF wireless safety and performance**; the OmniPod Insulin Management System has been tested and verified to ensure proper wireless communication between the Pod and PDM.
- **Electromagnetic interference**; the OmniPod Insulin Management System has been tested and successfully met all of the relevant sections (Radiated emissions, Electrostatic discharge immunity test, radiated radio frequency, electromagnetic field immunity, and Power frequency magnetic field immunity test) to satisfy compliance.

F. Conclusion

Insulet believes that the information and data provided clearly describes the OmniPod Insulin Management System and demonstrates that the device is adequately designed for the labeled indication for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate device and is suitable for the labeled indication for use.

Therefore, the proposed OmniPod Insulin Management System is considered to be substantially equivalent to the identified predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 7, 2012

Mr. Michael J. Doyle
Director Regulatory & Clinical Affairs
Insulet Corporation
9 Oak Park Drive
Bedford, Massachusetts 01730

Re: K122953
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: November 26, 2012
Received: November 28, 2012

Dear Mr. Doyle:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122953

Device Name: OmniPod Insulin Management System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.12.07 11:33:25 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122953