K131294

510(k) Summary

Submitter:	Insulet Corporation 9 Oak Park Drive Bedford, MA 01730 USA
Contact Person:	Tara N. Turney, MS, RAC Regulatory Affairs Manager Phone: 781-457-5284 Fax: 781-457-5011 Email: tturney@insulet.com
Date Prepared:	August 27, 2013
Trade Name:	OmniPod Insulin Management System
Common Name:	Insulin Infusion Pump
Classification:	Class II, LZG Pump, Infusion, Insulin 880.5725
Predicate Device:	OmniPod Insulin Management System K122953, Cleared December 7th, 2012
Device Description:	The OmniPod Insulin Management System is a tubeless insulin pump and is intended for intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. This system is comprised of two primary components, the insulin pump (pod) and the remote controller (Personal Diabetes Manager). The proposed device is a modification to the OmniPod Insulin Management System that removes the integrated blood glucose meter from the Personal Diabetes Manager.
Statement of Intended Use:	The OmniPod® Insulin Management System is intended for subcutaneous (below the skin) delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.
Summary of Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device.

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Summary of Non-Clinical Data:

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for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions Draft Guidance* and other guidance, as applicable.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 that the proposed device to be substantial equivalent to the predicate device:

- **Physical Characteristics**
- **Drop and Vibration**; the proposed device has been tested and successfully met all of the relevant requirements for drop and vibration testing per IEC 60601-2-24.
- **Software**; documentation was prepared and submitted for a MAJOR level of concern device in accordance with FDA's Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices.*
- **Electrical safety**; the proposed 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 proposed device has been tested and verified to ensure proper wireless communication between the Pod and PDM.
- **Electromagnetic interference**; the proposed device 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.

All testing met acceptance criteria.

Summary of Clinical Data:

Clinical data was not required for a determination of substantial equivalence for this device modification.

Conclusion from Data:

Insulet believes that the information and data provided in this submission clearly describes the proposed device 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 substantially equivalent to the identified predicate.

Insulet Corporation has demonstrated that the modified OmniPod Insulin Management System is substantially equivalent to the predicate device based upon indications for use, design, test results and the same fundamental scientific technology.

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

August 29, 2013

Ms. Tara Turney
Regulatory Affairs Manager
Insulet Corporation
9 Oak Park Dr.
Bedford, Massachusetts 01730

Re: K131294
Trade/Device Name: Omnipod Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Pump, Infusion, Insulin
Regulatory Class: Class II
Product Code: LZG
Dated: July 19, 2013
Received: July 29, 2013

Dear Ms. Turney:

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 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. 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,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division 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): K131294

Device Name: OmniPod Insulin Management System

Indications for Use: The OmniPod® Insulin Management System is intended for subcutaneous (below the skin) delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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