Class 1 Recall OmniPod Insulin Management System

See Related Information[22]

Date Posted	December 15, 2015
Recall Status[1]	Open
Recall Number	Z-0393-2016
Recall Event ID	72535[23]
Premarket Notification 510(K) Number	K122953[24]
Product Classification	Pump, Infusion, Insulin[25] - **Product Code** LZG[26]
Product	OmniPod®, Insulin Management System (US) Catalog Number: PODZXP420 Product Usage: The OmnniPod® 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.
Code Information	Lot Codes: L41880, L41881, L41892, L41895,L41897,L41898, L41899,L41900, L41901, L41902, L41903, L41904, L41905, L41906, L41907
Recalling Firm/ Manufacturer	Insulet Corporation 600 Technology Park Dr Ste 200 Billerica, Massachusetts 01821-4126
For Additional Information Contact	Same 978-600-7000
Manufacturer Reason for Recall	Pod's needle mechanism fails to deploy or there is a delay in the deployment of the needle mechanism.
FDA Determined Cause [2]	CHANGE CONTROL (GMP - GOOD MANUFACTURING PRACTICE): Process Change Control
Action	Insulet issued on 11/2/15 an URGENT: Field Safety Notification via Email notification and Federal Express. Letter describes the problem that certain lots of the pod's needle failed to deploy or there is a delay in the deployment of the needle. Customers not responding to the email or Federal Express will receive additional mailing and/or follow up phone calls. Call Customer Care at 1-855-407-3729 if you have any questions regarding this Field Safety Notification.
Quantity in Commerce	26,230.9 boxes
Distribution	Worldwide Distribution - US Nationwide and countries of Switzerland, Germany, and Israel.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = LZG and Original Applicant = INSULET CORPORATION[29]