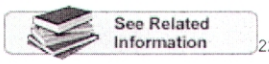
FDA

Class 2 Device Recall CADD Solis VIP



[22]

Date Initiated by Firm	October 31, 2016
Create Date	March 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1439-2017
Recall Event ID	76189[23]
Product Classification	Pump, infusion, pca[24] - **Product Code** MEA[25]
Product	CADD Solis VIP Ambulatory Infusion Pump, Model 21-21210, Reorder 21-2120-0102-15,
Code Information	1071155, 1076826, 1081258, 1081260, 1081275, 1082475, 1082511, 1082512, 1090347, 1090348, 1090349, 1091767, 1091768, 1091769, 1091770, 1091771, 1092395, 1100186, 1100188, 1100189.
Recalling Firm/ Manufacturer	Smiths Medical ASD, Inc. 1265 Grey Fox Rd Saint Paul MN 55112-6929
For Additional Information Contact	Smiths Medical Representative 651-633-2556
Manufacturer Reason for Recall	20 Pumps sold to the Finnish market contain a message in which one word in the message is mistranslated. When the user follows a specific set of key presses the pump will display the incorrect message. The message indicates that a Patient Controlled Analgesia (PCA) dose is unavailable because the pump is running. It should indicate that the PCA dose is not available because the pump is stopped. The function of the pump is unchanged and no patient injury can occur since no drug is being delivered.
FDA Determined Cause [2]	Software design
Action	Smiths Medical sent an Urgent Medical Device Field Safety Notice dated October 26, 2016, via FedEx on October 31, 2016. The letter described the Reason for Field Corrective Action, Risk to Health, and Instructions to Customers. Advised consignees to contact the Smiths Medical Service & Repair Department for the software to be loaded and to complete the Recall Confirmation Form and return it to Smith Medical via e-mail to FCA.Response@Smiths-medical.com. For further questions please call (651) 633-2556.
Quantity in Commerce	20
Distribution	Internationally to Finland
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.