**Class 2 Device Recall CADD Solis VIP**

**Date Initiated by Firm**
October 31, 2016

**Create Date**
March 10, 2017

**Recall Status**
Open, Classified

**Recall Number**
Z-1439-2017

**Recall Event ID**
76189

**Product Classification**
Pump, infusion, PCA - Product Code MEA

**Product**
CADD Solis VIP Ambulatory Infusion Pump, Model 21-21210, Reorder 21-2120-0102-15

**Code Information**
1071155, 1076926, 1081256, 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**
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 Smiths Medical via e-mail to FCAResponse@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

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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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrecs/recs.cfm?id=152490).

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