### Class 2 Recall Baxter Healthcare

**Date Posted:** April 27, 2015  
**Recall Status:** Open  
**Recall Number:** Z-1535-2015  
**Recall Event ID:** 70641  
**Premarket Notification 510(K) Number:** K051253  
**Product Classification:** Pump, Infusion, Pca - Product Code MEA  
**Product:** The Patient Control Module (PCM) is used in conjunction with a Baxter infusion as a single use device for the control of intermittent bolus doses of medication based on patient demand.

#### Code Information


#### Recalling Firm/Manufacturer

Baxter Healthcare Corp.  
1 Baxter Pkwy  
Deerfield, Illinois 60015-4625

#### For Additional Information Contact

Center for One Baxter  
800-422-9837

#### Manufacturer Reason for Recall

Potential for device malfunction resulting in flow when the device should not be flowing

#### FDA Determined

PRODUCTION CONTROLS: Process Control