

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Baxter Healthcare

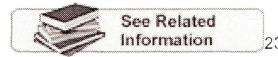


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**Class 2 Recall
Baxter Healthcare**



Date Posted	April 27, 2015
Recall Status¹	Open
Recall Number	Z-1536-2015
Recall Event ID	70641 ²⁴
Premarket Notification 510(K) Number	K051253 ²⁵
Product Classification	Pump, Infusion, Pca ²⁶ - Product Code MEA ²⁷
Product	The Patient Control Module (PCM) is used in conjunction with a Baxter infusor as a single use device for the control of intermittent bolus doses of medication based on patient demand.
Code Information	1) Product Code: 2C1067; Lots and Expiration Dates: Lot 11D001 , Expires 4/1/2014 ; Lot 11D068 , Expires 4/1/2014 ; Lot 11E048 , Expires 5/1/2014 ; Lot 11E084 , Expires 5/1/2014 ; Lot 11F050 , Expires 6/1/2014 ; Lot 11G019 , Expires 7/1/2014 ; Lot 11H019 , Expires 8/1/2014 ; Lot 11H074 , Expires 8/1/2014 ; Lot 11J042 , Expires 9/1/2014 ; Lot 11J078 , Expires 9/1/2014 ; Lot 11M078 , Expires 11/1/2014 ; Lot 11N027 , Expires 12/1/2014 ; Lot 12A020 , Expires 1/1/2015 ; Lot 12A037 , Expires 1/1/2015 ; Lot 12A050 , Expires 1/1/2015 ; Lot 12A095 , Expires 2/1/2015 ; Lot 12B040 , Expires 2/1/2015 ; Lot 12C033 , Expires 3/1/2015 ; Lot 12D016 , Expires 4/1/2015 ; Lot 12D041 , Expires 4/1/2015 ; Lot 12D089 , Expires 4/1/2015 ; Lot 12E004 , Expires 5/1/2015 ; Lot 12E010 , Expires 6/1/2015 ; Lot 12F036 , Expires 6/1/2015 ; Lot 12G032 , Expires 7/1/2015 ; Lot 12G034 , Expires 7/1/2015 ; Lot 12G057 , Expires 7/1/2015 ; Lot 12H012 , Expires 7/1/2015 ; Lot 12H033 , Expires 8/1/2015 ; Lot 12H077 , Expires 8/1/2015 ; Lot 12J047 , Expires 9/1/2015 ; Lot 12K008 , Expires 10/1/2015 ; Lot 12M036 , Expires 11/1/2015 ; Lot 12N031 , Expires 12/1/2015 ; Lot 13A016 , Expires 1/1/2016 ; Lot 13A084 , Expires 1/1/2016 ; Lot 13B037 , Expires 2/1/2016 ; Lot 13C018 , Expires 3/1/2016 ; Lot 13D012 , Expires 4/1/2016 ; Lot 13E009 , Expires 5/1/2016 ; Lot 13E034 , Expires 5/1/2016 ; Lot 13F044 , Expires 6/1/2016 ; Lot 13F058 , Expires 6/1/2016 ; Lot 13G026 , Expires 7/1/2016 ; Lot 13H025 , Expires 8/1/2016 ; Lot 13H081 , Expires 8/1/2016 ; Lot 13J007 , Expires 9/1/2016 ; Lot 13M052 , Expires 11/1/2016 ; Lot 13N008 , Expires 12/1/2016 ; Lot 14A019 , Expires 1/1/2017 ; Lot 14A033 , Expires 1/1/2017 ; Lot 14B015 , Expires 2/1/2017 ; 2) Product Code: 2C1067K; Lots and Expiration Dates: Lot 11E025 , Expires 5/31/2014 ; Lot 11H035 , Expires 8/31/2014 ; Lot 11N025 , Expires 12/31/2014 ; Lot 12D061 , Expires 4/30/2015 ; Lot 12F012 , Expires 6/1/2015 ; Lot 12K024 , Expires 10/31/2015 ; Lot 13A047 , Expires 1/31/2016 ; Lot 13H067 , Expires 8/31/2016 ; Lot 13N025 , Expires 12/31/2016 ; Lot 13N026 , Expires 12/31/2016 ; Lot 13N027 , Expires 12/31/2016 ; Lot 13N045 , Expires 12/31/2016
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