**Class 2 Recall SPECTRUM Pump**

See Related Information[22]

| | |
|---|---|
| **Date Posted** | October 01, 2014 |
| **Recall Status**[1] | Open |
| **Recall Number** | Z-2738-2014 |
| **Recall Event ID** | 69122[23] |
| **Premarket Notification 510(K) Number** | K042121[24] |
| **Product Classification** | Pump, Infusion[25] - **Product Code** FRN[26] |
| **Product** | SPECTRUM Pump, Model No. 35700BAX. Intended to be used for the controlled administration of intravenous fluids. |
| **Code Information** | Software Versions 5.02.06, 6.02.06, and 6.02.11; Affected Serial Numbers: 712090, 723687, 723842, 724966, 725820, 735977, 751130, 752124, 755174, 768538, 771990, 774743, 781406, 783736, 784698, 794466, 805797, 808901, 809113, 812462, 815932, 842120, 857926, 858672, 862085, 863721, 865630, 873459, 889597, 890260, 903748, 912619, 920574, 920589, 956346, 957394, 965402, 966684, 976931, 977550, 978361, 983979, 984066, 984129, 984475, 985946, 987538, 993445, 995291, 996014, 996389, 1013037, 1004377, 1014565, 1014962, 967887, 950671, and 938428. |
| **Recalling Firm/ Manufacturer** | Baxter Healthcare Corp.<br>25212 W. Illinois Route 120<br>Round Lake, Illinois 60073-9799 |
| **Manufacturer Reason for Recall** | One Service Technician may not have correctly serviced specific Sigma Spectrum Infusion Pumps according to established procedures during the time period of 5/5/2014 through 6/3/2014. |
| **FDA Determined Cause** [2] | OTHER/UNDETERMINED: Under Investigation by the firm |
| **Action** | Initial notification was initiated via telephone call by the Baxter Medina Service Center on 8/28/14 to all affected Sigma SPECTRUM Infusion Pump consignees. URGENT DEVICE CORRECTION Letters (dated 9/03/2014) were sent to the consignees via USPS first class mail on 9/03/14 formally informing them of the recall. The letters identified the affected product, the description of the issue, the hazard involved, as well as, the actions to be taken by customer. Customers are being instructed to immediately remove the pump from use and return the pump to Baxter for inspection. The firm will provide replacements. Customers are to contact Baxter Healthcare Medina at 800-356-3454 for technical questions regarding the letter. |
| **Quantity in Commerce** | USA: 56 units, Canada: 2 units |
| **Distribution** | Worldwide Distribution -- USA and Canada. |
| **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.