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Medical Device Recalls

Class 1 Recall
GemStar Medical Power Supply

Date Posted	October 24, 2014
Recall Status[1]	Open
Recall Number	Z-0096-2015
Recall Event ID	68047
Premarket Notification 510(K) Number	K060806
Product Classification	Pump, Infusion - **Product Code** FRN
Product	The GemStar Power Supply is an accessory for the GemStar Infusion Pump. It is a two piece assembled switching power supply. The Power Supply converts alternating current (AC) line input voltage of 120 or 240 V to an output to the device of 3.3 Volts DC.
Code Information	Desktop GemStar Power Supply List Number: 13072-05; 1) US Distribution Lot Numbers: 10115G1, 11121G1, 11122G1, 1123G1, 11124G1, 12143G1, 12144G1, 12178G1, 15185G1, 12195G1, 17214G1, 18217G1, 18219G1, 19225G1, 20233G1, 21242G1, 22251G1, 23259G1, 24271G1, 25280G1, 26289G1, 26290G1, 27293G1, 27297G1, 27300G1; 2) Foreign Distribution Lot Numbers: 11128G1, 12140G1, 12142G1, 12148G1, 14176G1, 15187G1, 15196G1, 16207G1, 16208G1, 18218G1, 19226G1, 19229G1, 20234G1, 21241G1, 22255G1, 23262G1, 24270G1, 25276G1, 26285G1, 27299G1, 27301G1
Recalling Firm/ Manufacturer	Hospira Inc. 275 N Field Dr Lake Forest, Illinois 60045-2579
For Additional Information Contact	Hospira Global Complaint Management 224-212-2000
Manufacturer Reason for Recall	The GemStar Infusion pump may not receive direct current (DC) power from the power supply. In one instance, smoke was observed and the GemStar pump was operating on battery power while connected to the 3 volt DC power supply.
FDA Determined Cause [2]	DESIGN: Process Design
Action	An URGENT MEDICAL DEVICE CORRECTION letter dated February 3, 2014 was sent to all direct accounts. The letter included specific instructions for how to handle and use the power supplies so as to minimize the chance of any device failures. There were additional instructions for customers to: 1) Inform potential users in their organization of the product of this notification; 2) Complete the attached reply form and return it to the fax number or e-mail address on the form (even if you do not have any affected product in inventory); 3) If the products were further distributed, their customers should be notified of the recall and asked to contact Stericycle at 888-641-9735 to receive a reply form; and, 4) if a potential user believes that their power supply is damaged for any reason, it should be removed from service and the user should contact Hospira Global Complaints at 800-441-4100 to report the concern. The letter further notes that there is no need to return fully functional power supplies (unless they malfunction).
Quantity in Commerce	US Distribution: 4,709 power supplies; Foreign Distribution: 7,425 power supplies
Distribution	Worldwide Distribution -- USA, including the states of AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS,

MT, NC, ND, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, and WY; and, the countries of Austria, Belgium, Brazil, Columbia, France, Germany, Greece, Netherlands, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, Turkey, and United Kingdom.

Total Product Life Cycle TPLC Device Report

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[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = FRN and Original Applicant = HOSPIRA, INC.

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