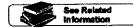
FDA Home³ Medical Devices⁴ Databases⁵

Medical Device Recalls

Class 1 Recall

GemStar Medical Power Supply



Date Posted

October 24, 2014

Recall Status¹

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

510(K) Database

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

Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- $5. \quad http://www.fda.gov/MedicalDevices/DeviceRegulation and Guidance/Databases/default.htm$

Page Last Updated: 11/08/2014

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Email FDA

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For Government For Press

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U.S. Department of Health & Human Services

Links on this page:

¹ For details about termination of a recall see <u>Code of Federal Regulations (CFR) Title 21 §7.55</u>

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