Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 5, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. – RECALL [Medical Device]

AFFECTED PRODUCT: **GemStar™ Docking Station used in conjunction with the GemStar infusion pump.**

SUMMARY: **Unclassified Recall; The recall is due to two potential malfunctions that may occur with the GemStar Docking Station.**

The products impacted by these issues are identified in the table below and have been in distribution since February 2002:

Impacted/ Affected Product Code	Issue	Potential to Occur in Conjunction with Products (Description)	Potential to Occur in Conjunction with List Numbers
13075	Fail to Power Up	GemStar Phase 3 pumps	13000, 13100, 13150
	Error Code 11/003	GemStar Phase 3 pumps or GemStar Phase 4 pumps	13000, 13100, 13150 13086, 13087, 13088

These products have been distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance or to obtain a copy of the Urgent Medical Device Correction letter and/or a reply form, please contact Stericycle at 1-866-792-5451 (M-F, 8am-5pm ET).**

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Recall -- Firm Press Release

Hospira Announces Urgent Nationwide Medical Device Correction For Gemstar Docking Station

Contact:
Consumer:
1-800-441-4100

Media:
224-212-2357

FOR IMMEDIATE RELEASE - May 2, 2014 - Hospira, Inc. (NYSE: HSP), announced today a nationwide medical device correction of the GemStar™ Docking Station (list number 13075), used in conjunction with the GemStar infusion pump. The correction is being taken following customer reports of two potential malfunctions that may occur with the GemStar Docking Station. The GemStar Docking Station is a separately sold accessory to the GemStar infusion pump and provides an alternate power source to the GemStar pump.

When the docking station is used in conjunction with a GemStar Phase 3 pump (List 13000, 13100 or 13150) the potential exists for the GemStar Phase 3 pump to fail to power up while connected to the docking station. When a GemStar Phase 3 (List 13000, 13100 or 13150) or GemStar Phase 4 pump (List 13086, 13087 or 13088) is used in conjunction with both a docking station and an external battery pack accessory (List 13073), there is a possibility that the GemStar pump will display error code 11/003 and give an audible alarm, indicating excessive input voltage from the external sources. If the GemStar pump detects what is perceived to be more than 3.6 Volts as measured on the external voltage input, the pump will stop the infusion. This will trigger an audible alarm and the device will display alarm code 11/003. Hospira previously distributed an Urgent Medical Device Correction notice to customers regarding these issues Feb. 18, 2014.

If a GemStar fails to power up or the 11/003 error code stops an infusion, a delay of therapy may occur. A delay or interruption in therapy has a worst case potential to result in significant injury or death. Healthcare professionals are advised to weigh the risk/benefit to patients associated with the use of the device when administering critical therapies. Customers should consider the use of an alternative pump, particularly in patients in which a delay/interruption in/of therapy could result in serious injury or death. To date, there have been no reports of death or serious injury associated with these malfunctions.

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13075	Fail to Power Up	GemStar Phase 3 pumps	13000, 13100, 13150

Error Code 11/003	GemStar Phase 3 pumps or GemStar Phase 4 pumps	13000, 13100, 13150 13086, 13087, 13088

There is no need to return the GemStar Docking Station at this time and Hospira recommends that users take the following actions:

1. To avoid a failure to power up, turn the pump on first, before connecting the pump with the docking station. This will prevent the failure to power up.
2. To mitigate the potential for an 11/003 error code, remove the external battery pack accessory (List 13073) from the docking station and pump prior to installing the pump into the Docking Station. If you use a docking station in conjunction with an external battery pack accessory (List 13073), this practice should not continue. Please contact Hospira to discuss an appropriate alternative option.

Customers should inform potential users of this product in their organizations of this notification. Users who experience a failure to power up or an 11/003 error code should report the issue to Hospira by calling 1-800-441-4100 (M-F, 8am-5pm CT) or email ProductComplaintsPP@hospira.com. For additional assistance or to obtain a copy of the Urgent Medical Device Correction letter and/or a reply form, please contact Stericycle at 1-866-792-5451 (M-F, 8am-5pm ET).

On May 1, 2013, Hospira announced that it would begin the process of retiring the GemStar family of infusion devices in accordance with the company's global device strategy. As of July 31, 2015, Hospira will consider the products within the GemStar Infusion System family retired and will no longer support them.

Adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This urgent medical device correction is being conducted with the knowledge of the FDA

About Hospira

Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill., and has approximately 17,000 employees. Learn more at www.hospira.com.

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