الموضوع: إشعار بمتابعة جهاز تحتوي على GemStar Pump- Single channel infusion device

الجهاز المعني بالموافقة:
- GemStar Pump- Single channel infusion device
- Traue Mark: Hospira Inc
- Local Representative:

بناءً على التقرير الصادر عن وكالة الـFDA، والنصوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عمل الصفوف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطًا:
- التقرير الصادر عن وكالة الـFDA

بيان:
- دائرة البرنامج والمشاريع
- المستشفيات الحكومية
- المخزونات

مديرية عام الصحة
Class 1 Recall
GemStar Infusion System

Data Posted
April 30, 2012

Recall Number
Z-1169-2013

Product
The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required. The GemStar Pump can be powered by AC mains adaptor, rechargeable battery pack, docking station, or two disposable AA alkaline batteries. When powered by batteries, the GemStar Pump is ideal for ambulatory patients. The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required.

Code Information
List Numbers: 13029, 13100, 13150

Recalling Firm/Manufacturer
Hospira Inc.
275 N Field Dr
Lake Forest, Illinois 60045-2579

Consumer Instructions
Contact the recalling firm for information

For Additional Information Contact
Mr. Chris Eustace
224-212-4892

Reason for Recall
Pump shutting off during use without warning.

Action
Hospira sent an important Device Information letter dated March 18, 2013, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to inspect the affected product for signs of leakage, corrosion or other damage prior to each use. In addition, each time the batteries are replaced the battery compartment should be inspected for damage. If a device exhibits damage caused by leakage, it should immediately be removed from clinical service and Hospira should be contacted at 1-800-441-4100 to arrange for return of the device for repair. If the product has been further distributed they should notify their consignees and confirm they have done so by returning the reply form to Stericycle. For questions regarding this recall call 224-212-4892.

Quantity in Commerce
List Number 13000: 25,119 pumps; List Number 13100: 185 pumps; List Number 13150: 13,497 pumps

Distribution
Worldwide Distribution - USA (nationwide) and internationally to Australia, New Zealand, China, Hong Kong, Taiwan, Japan, Korea, Philippines, Thailand, Malaysia, Canada, Austria, Bahrain, Belgium, Croatia, Denmark, Egypt, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Lebanon, Libya, Luxembourg, Malta, Netherlands, Norway, Oman, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, United Arab Emirates, Brazil, Chile and Colombia.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/ediri/devicesatfda/index.cfm
7. /scripts/PMN/pmnm.cfm
8. /scripts/cfm/cfm.cfm
9. /scripts/PMN/PMN/TextSearch.cfm
10. /scripts/PMN/PMN/TextSearch.cfm
11. /scripts/PMN/PMN/TextSearch.cfm
12. /scripts/PMN/PMN/TextSearch.cfm
13. /scripts/PMN/PMN/TextSearch.cfm
14. /scripts/PMN/PMN/TextSearch.cfm
15. /scripts/PMN/PMN/TextSearch.cfm
16. /scripts/PMN/PMN/TextSearch.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=117159
7/3/2013
Class 1 Recall
GemStar Infusion System

Date Posted
April 30, 2013

Recall Number
Z-1170-2013

Product
The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required. The GemStar Pump can be powered by AC mains adaptor, rechargeable battery pack, docking station, or two disposable AA alkaline batteries. When powered by batteries, The GemStar Pump is ideal for ambulatory patients. The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required.

Code Information
List Numbers: 13085, 13087, 13088

Recalling Firm/Manufacturer
Hospira Inc.
275 N Field Dr
Lake Forest, Illinois 60045-2579

Consumer Instructions
Contact the recalling firm for information

For Additional Information Contact
Mr. Chris Eustace
224-212-4892

Reason for Recall
Pump shut off during use without warning.

Action
Hospira sent an important device information letter dated March 18, 2013, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to inspect the affected product for signs of leakage, corrosion or other damage prior to each use. In addition, each time the batteries are replaced the battery compartment should be inspected for damage. If a device exhibits damage caused by leakage, it should immediately be removed from clinical service and Hospira should be contacted at 1-800-444-1100 to arrange for return of the device for repair. If the product has been further distributed they should notify their consignees and confirm they have done so by returning the reply form to Stericycle. For questions regarding this recall call 224-212-4892.

Quantity in Commerce
List Number 13085: 296 pumps; List Number 13087: 45,376 pumps; List Number 13088: 23,942 pumps

Distribution
Worldwide Distribution - USA (nationwide) and internationally to Australia, New Zealand, China, Hong Kong, Taiwan, Japan, Korea, Philippines, Thailand, Malaysia, Canada, Austria, Bahrain, Belgium, Croatia, Denmark, Egypt, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Lebanon, Libya, Luxembourg, Malta, Netherlands, Norway, Oman, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, United Arab Emirates, Brazil, Chile and Colombia.