الموضوع: إشعار بمتابعة جهاز طبي
Infusion Pumps, Multitherapy, Various Plum A+ Infusion Pumps

المتابعة:

- Infusion Pumps, Multitherapy, Various Plum A+ Infusion Pumps
- Trade Mark: Hospira Inc
- Local Representative:

FDA

بناء على التقرير الصادر عن وكالة ال
الذي يحذر فيه من استعمال الصفタイプ المذكور أعلاه بسبب وجود خلل في عمله مما قد يؤثر على
سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التقرير الصادر عن وكالة ال

FDA

البليغ

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

وينبغي مطابقة الأصل

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Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

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Class 2 Recall
Plum A+ Single Channel Infusion Pumps

Date Posted
March 14, 2011

Recall Number
Z-1644-2011

Product
Plum A+ Single Channel Infusion Pumps; Hospira, Inc., Lake Forest, IL 60045; the pumps were sold under the following configurations: a) list 11971; b) list 11973; c) list 12391 - software version 10.3; d) list 12391 - software version 11.3; e) list 20792 - Hospital MedNet Software; f) list 20792 - Driver The Plum A+ dual-line volumetric infusion system designed to meet the growing demand for hospital-wide, as well as alternate site and home healthcare, standardization. With their primary line, secondary line, and piggyback fluid delivery capability, the Plum A+ is suited for a wide range of medical/surgical and critical care applications. Full compatibility with LifeCare Plum Series administration sets and accessories and the LifeShield® needless protection systems makes the Plum A+ a convenient and cost-effective infusion system.

Code Information
a) list 11971 - serial numbers 0013120009 through 0096072443; b) list 11973 - serial numbers 0012570148 through 0012579183; c) list 12391 - serial numbers 0013840001 through 0013890171; d) list 20792 - serial numbers 0015441019 through 0015459165; e) list 20792 - serial numbers 0016061001 through 0018787700

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
Ms. Ilenea Quiones
224-212-2000

Reason for Recall
Hospira has received customer reports of the Plum A+ infusion pumps with no audible alarm conditions, which have been associated with failure of the piezoelectric assembly due to component quality issues.

Action
The firm, Hospira, sent "URGENT DEVICE RECALL" letters dated February 14, 2011 to their customers on the same date. The letter described the product, problem and action to be taken by the customers. The Customers/Clincians were instructed to weigh the risk associated with continued use of the device versus removal from service. If they elect to continue the devices, they were provided with instructions to perform alarm tests prior to each clinical use (during their pump cleaning process). If the alarm is not audible, they were instructed to discontinue use of the pump and contact Hospira Global Product Safety and Complaints at 1-800-441-4100. The customers were requested to contact Hospira Advanced Knowledge Center at 1-800-241-4002 for technical assistance. The accounts were also requested to complete the attached Reply Form and return it to Hospira via fax at 1-888-216-7330.

Quantity in Commerce
144,477 pumps

Distribution
Worldwide distribution: United States including the U.S. Virgin Islands and Puerto Rico, and countries including: Argentina, Australia, Bahamas, Barbados, Belgium, Brazil, Canada, Chile, Colombia, Costa Rica, Denmark, Dominican Republic, France, Greece, Hong Kong, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Korea, Kuwait, Lebanon, Libya, Malaysia, Mexico, Netherlands, New Zealand, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Saudi Arabia, Singapore, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, Uruguay, United Arab Emirates and Vietnam.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=97093
1/15/2013