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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ١٣/١/٢٧٢٤
بيروت، في: ٢٢ كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

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

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

بناء على التقرير الصادر عن وكالة ال FDA
الذي يحذر فيه من استعمال الصنف 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

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمّار

وثيقة مطابقة للأصل
بيروت في ٢٦ كانون الثاني ٢٠١٣
رئيس قسم الدروس والقضايا والعلاقات الصحية والدولية
عيد ضومط

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U.S. Food & Drug Administration

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Class 2 Recall
Plum A+ Single Channel Infusion Pumps

See Related Information[20]

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 - software version 10.3 c) list 12391 - software version 11.3 d) list 20679 - Hospira MedNet Software e) 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® needleless protection systems makes the Plum A+ a convenient and cost-effective infusion system.
Code Information	a) list 11971- serial numbers 0013120009 through 0099072443; b) list 11973 - serial numbers 0012570148 through 0012579183; c) list 12391 - serial numbers 0013840001 through 0013890171; d) list 20679 - 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. Ileana Quinones 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 Customer/Clinicians 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.

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