Class I Medical Device Recall: CareFusion Alaris Pump Module Model 8100

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: June 29, 2012

Product: Alaris Pump Module, model 8100

Model Numbers: Model 8100 modules. Affected serial numbers are available on the CareFusion website [1]

Range of Manufacturing and Distribution Dates: Affected pumps were manufactured from August 1, 2010, to July 31, 2011.

Intended Use: The Alaris Pump Module, model 8100, is a part used with the Alaris electronic infusion pump system. Electronic infusion pumps deliver controlled amounts of medications or other fluids to patients through intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration. It is indicated for use on adults, pediatrics, and neonates.

Recalling Firm:
CareFusion 303, Inc.
10020 Pacific Mesa Boulevard
San Diego, California 92121-4386

Reason for Recall: CareFusion has received reports of customers experiencing motor stalls during infusion with the Alaris Pump Module, model 8100. Most of the motor stalls reported have occurred at high infusion rates (typically over 900 ml/hr). However, the firm cannot rule out the possibility of motor stall occurrence at lower infusion rates. When a motor stall occurs, the Alaris PC unit and the Alaris Pump Module display the visual error code 242.4030 with an audible alarm that is followed by a termination of infusion. Termination of infusion, especially in high risk patients, could result in serious injury or death.

Public Contact: Customers with questions about this recall may contact the CareFusion Support Center at 1-888-562-6018, from 7am to 5pm (Pacific).

FDA District: Los Angeles

FDA Comments:

On July 20, 2012, CareFusion sent an urgent Medical Device Recall Notification [2] to customers who purchased the Alaris Pump Module, model 8100. In that letter, the

firm alerted customers to the potential risk to patient health caused by this failure and it advised clinicians to weigh the risk/benefit to patients before continuing to use this device. The following instructions were also communicated to customers:

- Facilities administering high risk infusions to high risk patients should consider using alternative devices, if available. If alternative devices are not available, facilities should consider having additional devices immediately available as backup.
- If a motor stall occurs with a pump, facilities should remove the pump module from use and contact the CareFusion Support Center at 1-888-812-3229 from 7am to 5pm (Pacific).

CareFusion stated that it is continuing to monitor these incidents and investigate the cause of failure. CareFusion will notify customers as new information becomes available.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [3] either online, by regular mail or by FAX.

Additional Links:

- CareFusion Letter to Customers [2]

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http://www.mdtmag.com/news/2012/08/class-i-medical-device-recall-carefusion-alaris-pump-module-model-8100?qt-video_of_the_day=0

Links:
[1] http://www.carefusion.com/pdf/Alerts_and_Notices/Alaris/Alaris_LVP_8100_motor_stall_serial_number_list_ver01.pdf
[2] http://www.carefusion.com/customer-support/alerts-notices/medical-device-recall-alaris-pump-module-8100-intermittent-motor-stall.aspx
[3] http://www.fda.gov/Safety/MedWatch/default.htm