Class I Medical Device Recall: SIGMA Spectrum Infusion Pump Model 35700

U.S. Food & Drug Administration

Recall Class: I

Date Recall Initiated: September 15, 2010

Product: SIGMA Spectrum Infusion Pump Model 35700
Serial numbers ranging from 706497 to 724065

The affected units were manufactured from October 2006 to March 2008.

Use: The SIGMA Spectrum Infusion Pump is intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration.

Recalling Firm:

Sigma International General Medical Apparatus, LLC
711 Park Avenue
Medina, New York 14103-1036

Reason for Recall:

These units may fail suddenly causing inaccurate flow conditions during use, ranging from back flow to over-infusion, including free flow. The pump does not issue an alarm when this occurs. These conditions could result in serious injury or death.

Public Contact:

Customers may contact the company at 1-866-482-2893, Monday through Friday, 8 AM though 5 PM (Eastern Time)

FDA District: New York Downstate

FDA Comments:

On or about September 15, 2010, the company sent its customers a recall notice (see under **Useful Links** below) by certified mail. The letter informed the company’s customers about the recall since these units may fail suddenly causing

inaccurate flow conditions during use.

Customers were instructed to check their inventory to verify whether their serial numbers fall within the range of pumps being recalled. Due to the possible failure of these units, SIMGA is taking the precautionary measure of servicing or replacing all affected Spectrum infusion pumps and is requiring the return of the recalled devices to its facility.

SIGMA has provided the following instructions for users:

1. **DO NOT USE the affected Spectrum infusion pumps on patient populations where inaccurate flow, ranging from back flow to over-infusion, including free flow, could result in serious adverse health consequences or death.**
2. **DO NOT USE on neonatal patients.**
3. If the facility does not have acceptable alternative methods for delivering therapy, the user should weigh the risks and benefits for the continued use of the affected pumps.
4. **If these pumps must be used, SIGMA recommends the following actions which may reduce the risk.**
    1. For pediatric and adult patients, an add-on buretrol may limit the amount of an over-infusion if the failure occurs. Always follow the buretrol manufacturer’s instructions.
    2. Consider using air-eliminating filters. Under free flow conditions, pumps cannot stop fluid flow. If air is in the line with fluid, the air will also infuse.
    3. 3Frequently observe that the drip rate (mL/hr) compares to the programmed pump flow. Also make an observation of the container volume to make sure it is correct. If a discrepancy is observed, immediately remove the pump from service and treat the patient as appropriate.

SIGMA additionally provided instructions to customers for the return of affected pumps.

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 the FDA’s MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail, or by FAX.

Useful Links:

- Spectrum Pump Voluntary Recall [2]

SOURCE [3]

Source URL (retrieved on *12/19/2013 - 1:23pm*):
http://www.mdtmag.com/news/2010/11/class-i-medical-device-recall-sigma-spectrum-infusion-pump-model-35700

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.sigmapumps.com/Recall/
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm233683.htm