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Medical Devices

Edwards Lifesciences Inc., Aquarius Hemodialysis System

Recall Class: Class I

Product Name: Aquarius Hemodialysis System

Model Number: GEF09800

This product has been manufactured from June 2008 to the present.

Date Recall Initiated: March 16, 2009

Use:

A Hemodialysis system is used to clean waste products and extra fluid from the body after the kidneys have failed. It also monitors the amount of fluid going into and out of the patient.

Recalling Firm:

Edwards Lifesciences, LLC
1 Edwards Way
Irvine, California 92614-5688

Reason for Recall:

Edwards Lifesciences is conducting an Urgent Product Recall for the Aquarius Hemodialysis System because of reports of clinically significant fluid imbalance. When a certain level of fluid imbalance is detected, the Aquarius will trigger an alarm. However, users are able to override this alarm and continue therapy. It is possible to remove too much fluid from or replace too much fluid to the patient. In repeated cases, this imbalance increases, and may result in serious injuries or death.

Public Contact:

Baxter International, Inc. is the U.S. distributor of the Aquarius. For questions regarding the Aquarius, contact the Baxter Clinical Help Line at 1-888-736-2543.

FDA District: Los Angeles

FDA Comments:

On January 11, 2010, the company sent its customers an "Urgent Product Recall" letter. It included the:

- description of the affected product, problem, and potential hazard
- advice on action to be taken
- revised device labeling
- information concerning the planned software upgrade to prevent users from bypassing the fluid balance alarm more than five times in a 20-minute period
- instruction to pass the notice on and inform all other employees within the company/organization that needed to be aware of the problem
- instruction to transfer the notice to other organizations which
 - this action had an impact
 - other organizations may have received the potentially affected devices through a transfer

The "Urgent Product Recall" letter updates and expands the "Field Safety Notice" sent to customers on March 16, 2009.

Class 1 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 experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by FAX.

Useful Link:

- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)¹