

FDA News

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Media Inquiries:
301-827-6242
Consumer Inquiries:
888-INFO-FDA

Cardinal Health 303, Inc. Signs Consent Decree with FDA Agrees to Correct Manufacturing Deficiencies

The U.S. Food & Drug Administration (FDA) today announced that Cardinal Health 303 Inc. (Cardinal 303), formerly known as Alaris Medical Systems, Inc., and three of its top executives, have signed a consent decree for condemnation and permanent injunction related to their Signature Edition (SE) infusion pumps. The infusion pumps have a design defect referred to as "key bounce" which may cause the pump to recognize a single key stroke as a double key stroke. The "key bounce" problem poses a risk to public health due to a potential over-infusion of medications.

Cardinal 303 has agreed to stop manufacturing and distributing all models of the SE infusion pumps until Cardinal 303 corrects manufacturing deficiencies and until the devices are made in compliance with the current good manufacturing practice (CGMP) requirements and the Quality System (QS) regulation for medical devices.

Infusion pumps are electronic devices intended to control delivery of solutions and medications to patients. They are used in situations where medication must be administered intravenously or through other routes, in a continuous or intermittent manner, for a prolonged period of time.

Under the terms of the consent decree, the company has agreed to take necessary measures to ensure compliance with the CGMP requirements and the QS regulation by all of its facilities that design, manufacture, process, pack, label, hold, or distribute SE infusion pumps. The decree was signed by Dwight Winstead, Cardinal 303's President and Chief Operating Officer, David L. Schlotterbeck, the company's Chairman and Chief Executive Officer, and William H. Murphy, the company's Senior Vice President of Quality and Regulatory Affairs. The decree also requires the company to retain an independent expert consultant to conduct inspections of its SE infusion pump facilities and certify to FDA that corrections have been made. FDA will continue to monitor these activities through its own inspections.

Under the consent decree, FDA will allow Cardinal 303 to continue to service and repair SE infusion pumps that were already in the hands of customers before entry of the decree. The company is also required to submit to FDA an acceptable detailed corrective action plan to bring the SE infusion pumps currently in use in the United States into compliance with the Federal Food, Drug, and Cosmetic Act.

The decree was entered in the United States District Court for the Southern District of California on February 8, 2007.

On August 25, 2006, the U.S. Marshals seized several lots of Cardinal 303's SE Gold infusion pumps located at the company's manufacturing facility in San Diego, California. The seizure was intended to

ensure that the infusion pumps are not distributed unless the problem is corrected. Cardinal 303 voluntarily suspended production, sales, repair, and installation of SE infusion pumps following the seizure.

On August 15, 2006, the company also voluntarily initiated a field corrective action for all SE infusion pumps, which consisted of sending letters and warning labels to its customers concerning the "key bounce" problem. The FDA has classified this action as a Class I recall (a situation where there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death). A copy of the company's letter to customers is available on the company's website at www.cardinalhealth.com/alaris.

FDA previously issued warning letters to the company, outlining deviations from the CGMP requirements and QS regulation. The company was given opportunities to correct the violations, but failed to take appropriate actions.

After corrective actions under the decree are completed and Cardinal 303 has been allowed to resume manufacturing and distribution, the firm will hire an independent auditor to conduct audit inspections of its SE infusion pump facilities at least once a year for no less than four years. Results of these audit inspections will be reported directly to FDA. If Cardinal 303 fails to comply with any provision of the decree, or violates the Act or FDA regulations, FDA may order the firm to again cease manufacturing and distributing, recall the products, or take other action.

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