Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Smiths Medical

AUDIENCE: Patient, Health Professional, Risk Manager, Pediatrics

ISSUE: Smiths Medical is recalling Medfusion 3500 and 4000 Syringe Infusion Pumps for eight software malfunctions that affect different serial numbers and software versions. These malfunctions may cause serious harm or death to patients from under- or over-infusion, or delays in the delivery of critical medications to patients.

Smiths Medical states have been a total of 7 serious injuries and one death reported related to these issues. The Customer Notification identifies the injuries and/or deaths associated with each software issue.

For more information about this recall, click on the red button **"Read Recall"** below.

BACKGROUND: Smiths Medical Medfusion 4000 and 3500 Syringe Infusion Pumps are used to give fluids to patients in precisely controlled amounts. They deliver blood or blood products, lipids, drugs, antibiotics, enteral feedings and other therapeutic fluids through infusion tubing into a patient's vein or through other cleared routes of administration. Syringe pumps are primarily used in the neonatal and pediatric populations or in operating rooms and intensive care units for the adult population.

RECOMMENDATIONS: Smiths Medical sent an Urgent Medical Device Correction letter to customers on April 19, 2022. The letter included an overview of each issue, the affected pump models, the potential risk to patients, and recommended actions for clinicians and for biomedical engineers for several issues. Smiths provided additional instructions to customers:

- Locate all affected pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.
- As indicated in the Operator's Manual, if the Medfusion pump is used to deliver life-sustaining medications, ensure an additional pump is available for situations where an interruption in infusion could be dangerous.

Complete and return the response form to the company within 10 days of receipt to acknowledge your understanding of this notification.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.