Class 2 Device Recall Siemens

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See Related Information[21]

Date Posted	April 16, 2014
Recall Status[1]	Open
Recall Number	Z-1460-2014
Recall Event ID	67780[22]
Premarket Notification 510(K) Number	K971452[23]
Product Classification	Table, Radiographic, Non-Tilting, Powered[24] - **Product Code** IZZ[25]
Product	AXIOM Vertix MD Trauma systems radiographic X-ray
Code Information	AXIOM Vertix MD Trauma systems (material no. 08908290) with serial numbers 1022 through 1058.
Recalling Firm/ Manufacturer	Siemens Medical Solutions USA, Inc 51 Valley Stream Pkwy Malvern, Pennsylvania 19355
For Additional Information Contact	Customer Support 610-219-6300
Manufacturer Reason for Recall	There is a potential issue and possible hazard to patients when using the AXIOM Vertix MD Trauma systems. In rare cases, steel ropes inside the lift column of the system can be defective without triggering the safety lock, which can result in the U-arm dropping down unexpectedly during movement in vertical direction, potentially causing serious injury.
FDA Determined Cause [2]	DESIGN: Component Design/Selection
Action	Siemens sent a Safety Advisory Notice dated March 5, 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were advised as a first check it is strongly recommended for the users to check whether metallic dust or rubbed off parts of metal are visible underneath the lifting column or around the system. If this is the case, it is strongly recommended to immediately stop using the Vertix MD Trauma system and call the local Siemens service. To avoid any risk until the implementation of the modification mentioned below, it is furthermore strongly recommended to perform up/down movements of the lifting column not directly above the patient, but complete the vertical movement beside the patient and then move the system horizontally above the patient. We appreciate your understanding and cooperation with this Safety Advisory Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Safety Advisory Notice is placed in the system's instructions for use until the update has been installed. If you have sold or otherwise disposed of this equipment and it is no under your control, we kindly ask that you forward this Safety Advisory Notice to the new user of the equipment. Please also inform us about the new owner of the equipment. We apologize for any inconvenience this may cause. Further questions please call (610) 219-6300.
Quantity in Commerce	2
Distribution	US Distribution including MO and OH.
Total Product Life Cycle	TPLC Device Report[26]