Class 2 Device Recall Cardinal, Digital Bariatric Scale

See Related Information[22]

Date Initiated by Firm	December 23, 2015
Create Date	June 01, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2217-2017
Recall Event ID	76975[23]
Product Classification	Scale, stand-on, patient[24] - **Product Code** FRI[25]
Product	Cardinal, Digital Bariatric Scale 1) model 6876, Cap 600 and 2) model 6868 Cap 1000
Code Information	None.
Recalling Firm/ Manufacturer	Cardinal Scale Mfg Co 203 E Daugherty St Webb City MO 64870-1929
For Additional Information Contact	Mark Levels 417-673-4631
Manufacturer Reason for Recall	One complaint of a seat on a scale failing unexpectedly which can cause an injury.
FDA Determined Cause [2]	Device Design
Action	On 12/23/2015, the recalling firm sent a letter to their customers. The letter accompanied a kit to be installed immediately upon receipt. For assistance with installation contact technical service department at 866-254-8261.
Quantity in Commerce	975 scales
Distribution	Worldwide distribution - US Nationwide in the states: Alabama, California, Colorado, Connecticut, Florida, Georgia, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, NEW JERSEY, New York, NORTH CAROLINA, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Product was also distributed to the following foreign countries: Canada, Hong Kong, Kuwait, Pakistan,
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.