FDA

Class 2 Device Recall ROIA Anterior Delivery Device

See Related Information[22]

Date Initiated by Firm	August 29, 2016
Create Date	October 05, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0045-2017
Recall Event ID	75068[23]
510(K)Number	K082262[24] K090507[25] K113027[26] K153495[27]
Product Classification	Orthopedic manual surgical instrument[28] - **Product Code** LXH[29]
Product	ROI-A Anterior Delivery Device. Orthopedic manual surgical instrument. Model number: SI-ROIA-0023 Auxiliary instrument used in the ROI-A-ALIR cage system: Spinal intervertbral body fusion device.
Code Information	Lot # 2295101A, 2295101A-R, 2296101A-R
Recalling Firm/ Manufacturer	LDR Spine USA, Inc. 13785 Research Blvd Ste 200 Austin TX 78750-1895
For Additional Information Contact	Mea Amor 512-344-3429
Manufacturer Reason for Recall	The ROI-A Anterior Delivery Device T-Handle, part number SI-ROIA-0023 has experienced binding of the rotation of the t-handle. There have been no reports of patient injury
FDA Determined Cause [2]	Device Design
Action	The firm, LDR, contacted affected consignees via phone and then sent a follow up email dated 9/8/16. The phone script and email described the product, problem and actions to be taken. The consignees were instructed to promptly return the instrument using the RMA#1180. The firm will perform a rework that prevents the binding to occur. If you have any question, contact the Quality Engineering Manager by email: ron.musselman@zimmerbiomet.com, phone: 512-344-3436 or Field Inventory Manager - US Supply Chain or phone: 512-344-3436.
Quantity in Commerce	24 units
Distribution	US Distribution to states of: GA, OR, FL, KY, NC, AR and PA.
Total Product Life Cycle	TPLC Device Report[30]

[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[31].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.