### Class 2 Device Recall ROIA Anterior Delivery Device

**Date Initiated by Firm**  
August 29, 2016

**Create Date**  
October 05, 2016

**Recall Status**  
Open, Classified

**Recall Number**  
Z-0045-2017

**Recall Event ID**  
7506823

**510(K)Number**  
K09226224, K09050725, K11302728, K15349627

**Product Classification**  
Orthopedic manual surgical instrument - Product Code LXU

**Product**  

**Code Information**  
Lot # 2295101A, 2295101A-R, 2295101A-R

**Recalling Firm/Manufacturer**  
LDR Spine USA, Inc.  
13785 Research Blvd Ste 200  
Austin TX 78750-1695

**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**  
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.muselmam@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

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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.

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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrec/res.cfm?id=149274  
11/7/2016