Class 2 Device Recall Concorde Lift

Date Initiated by Firm  July 26, 2017
Create Date  March 02, 2018
Recall Status  Open, Classified
Recall Number  Z-0849-2018
Recall Event ID  7907223
Product Classification  Orthopedic manual surgical instrument - Product Code LXH
Product  Concorde Lift Torque Limiting Handle.
Recalling Firm/Manufacturer  DePuy Orthopaedics, Inc.
325 Paramount Dr
Raynham MA 02767-5199
For Additional Information Contact  Christina Corbett
508-880-8100
Manufacturer Reason for Recall  Potential for Intra-operative breakage of driver tips
FDA Determined Cause  Under Investigation by firm
Action  On August 1, 2017, an Urgent Product Recall notice titled "CONCORDE LIFT DRIVER Driver Shaft and Torque Handle" was mailed to customers that received the affected instruments. The letter described the issue, potential hazard, and actions to be taken. The notice instructs customers to cease further distribution or use and to contact a DePuy Synthes Spine sales consultant to return the products subject to recall. Customers are to review, complete, sign, and return the business reply form provided to the firm within 5 business days of receipt of the notification. A copy of the notice should be forwarded to all staff that need to be informed, as well as, any facility that the affected device was further distributed to. Customers should direct any questions regarding this recall to their DePuy Synthes Spine Sales Consultant or the Clarke Madigan, DePuy Synthes Spine Recall Coordinator, at 508-828-609 or DPYUS-SpineFieldActions@tjs.jnj.com.
Quantity in Commerce  130 units total
Distribution  Nationwide Distribution
Total Product Life Cycle  TPLC Device Report

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 here.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161277