Class 2 Device Recall Concorde Lift

See Related Information [22]

Date Initiated by Firm	July 26, 2017
Create Date	March 02, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0849-2018
Recall Event ID	79072[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	Concorde Lift Torque Limiting Handle. Must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine.
Code Information	Product code: 287804102, Lot number: 122315-B R, 122315-A R, 041117A.
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 [2]	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@its.jnj.com.
Quantity in Commerce	130 units total
Distribution	Nationwide Distribution
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].