FDA

Class 2 Device Recall LATARJET EXPERIENCECombo Screw Driver

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See Related Information[22]

Date Initiated by Firm	May 12, 2017
Create Date	June 20, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2615-2017
Recall Event ID	77252[23]
510(K)Number	K110763[24] K091694[25] K083096[26]
Product Classification	Screw, fixation, bone[27] - **Product Code** HWC[28]
Product	DePuy Mitek LATARJET EXPERIENCE-Combo Screw Driver Product Code: 288211 Product Usage: The Latarjet Cortical Screw set is intended to treat recurrent shoulder instability by supporting the anteroinferior glenoid with a bony graft
Code Information	GTN: 01)10886705026890, Lot codes: 16D02, 16E01, 16J01, 17A01, 17B01, 17B02
Recalling Firm/ Manufacturer	DePuy Mitek, Inc., a Johnson & Johnson Co. 325 Paramount Dr Raynham MA 02767-5199
For Additional Information Contact	SAME 508-880-8100
Manufacturer Reason for Recall	Combo Screw Driver (Product Code 288211) tip has the increased potential to break intra-operatively when being used at an angle off-axis to screw
FDA Determined Cause [2]	Component design/selection
Action	DePuy Mitek issued recall letter dated May 12, 2017 advising of the problem and requesting return of the product. A Response Form is to be completed and returned. Questions: contact your DePuy Synthes Mitek Sales Consultant or Carolyn Somerville, DePuy Mitek, Inc. (via telephone: 508.828.3647 Fax: 508.828.3762 or via email: DPYUS-MitekFieldActions@its.jnj.com).
Quantity in Commerce	173 units
Distribution	US: AZ, CA, CO, GA, MA, MI, OH, WA Foreign: Austria, Australia, Belgium, France, Germany, Spain, Switzerland, Netherlands, Poland, UK
Total Product Life Cycle	TPLC Device Report[29]

[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[30].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.