Class 2 Device Recall DePuy Synthes orthopedic instruments

See Related Information[22]

Date Initiated by Firm	January 06, 2017
Create Date	June 08, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2317-2017
Recall Event ID	76023[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	DePuy Synthes various orthopedic instruments modified by U.S. Distributors These instruments are used in various orthopedic procedures
Code Information	Unknown
Recalling Firm/ Manufacturer	DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw IN 46582-3994
For Additional Information Contact	Tai L. Holmes-Johnson 574-371-4577
Manufacturer Reason for Recall	Products were made outside of Quality System Regulation, and potentially outside of premarket submission (510k/PMA) for certain devices. The safety or effectiveness of these devices cannot be assured.
FDA Determined Cause [2]	Vendor change control
Action	DePuy Synthes sent an URGENT INFORMATION RECALL NOTICE FOR INSTRUMENTS MODIFIED BY U.S. DISTRIBUTORS dated January 6, 2017, to all affected customers. . Customerss were instructed to identify all medical facilities that may have used or received the affected instruments and identify the modified instruments used at each facility. This information was to be used to generate Reconciliation Forms for each impacted Medical Facility. The Reconciliation Forms and URGENT INFORMATION RECALL NOTICE FOR INSTRUMENTS MODIFIED BY U.S. DISTRIBUTORS recall notifications were then delivered by DePuy Synthes Sales Consultants to the affected medical facilities. Instructions in the URGENT INFORMATION RECALL NOTICE FOR INSTRUMENTS MODIFIED BY U.S. DISTRIBUTORS provided to the medical facilities included the following: Please take the following actions: " Please immediately cease using the modified instruments identified in the attached Reconciliation Form. Your U.S. DePuy Synthes Sales consultant will work with your facility to locate and replace any affected instruments. " If your facility is using an instrument that was created or modified by a DePuy Distributor at the request of a surgeon, and it is not listed on the attached Reconciliation Form, please contact your DePuy Synthes Sales Consultant for an evaluation to determine if the instrument should be returned and replaced. WI-9956 | Rev 5 | Attachment B2 " Return Affected Instruments: o Medical facilities are to determine if any of the recalled instruments are still on hand by working with your U.S. DePuy Synthes Sales Consultant, and return affected devices immediately to their U.S. DePuy Synthes Sales Consultant or return them to DePuy Orthopaedics, Inc. for credit following normal purchasing procedures. o Note: These instruments may be on consignment at your

	facility. " Reconciliation Form: Complete the Reconciliation Form and return to your U.S. DePuy Synthes Sales Consultant or
Quantity in Commerce	345
Distribution	Nationwide Distribution to: AZ CA IA IL IN LA MA MD ME MI MN PA VA
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].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=76023
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LXH
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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