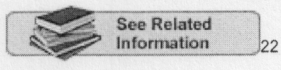
Class 2 Device Recall ACTIS Flex Reamers



[22]

Date Initiated by Firm	October 25, 2016
Create Date	November 21, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0650-2017
Recall Event ID	75540[23]
510(K)Number	K150862[24]
Product Classification	Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate[25] - **Product Code** MEH[26]
Product	ACTIS Flex Reamers SZ 0/1; 2/3; 4/5; 6/7; 8/9; 10/11; 12, Product is sold non-sterile, these instruments are packed non-sterile, within a rigid tube with foam protectors, with label and IFU
Code Information	Product Codes: 201001210, ACTIS FLEX REAMER SZ 0/1, GTIN: 10603295434818; 201001220, ACTIS FLEX REAMER SZ 2/3, GTIN: 10603295434870; 201001230, ACTIS FLEX REAMER SZ 4/5, GTIN: 10603295434849; 201001240, ACTIS FLEX REAMER SZ 6/7, GTIN: 10603295434856; 201001250, ACTIS FLEX REAMER SZ 8/9, GTIN: 10603295434863; 201001260, ACTIS FLEX REAMER SZ 10/11, GTIN: 10603295434825; 201001270, ACTIS FLEX REAMER SZ 12, GTIN: 10603295434832
Recalling Firm/ Manufacturer	Depuy Orthopaedics Inc. 700 Orthopaedic Dr Warsaw IN 46582-3994
For Additional Information Contact	Kim Earle, M.S. 574-371-4917
Manufacturer Reason for Recall	DePuy Orthopaedics, Inc. is issuing a voluntary recall for all lots of the ACTIS Flex Reamers due to the instruments breaking and potentially leaving pieces in the patient.
FDA Determined Cause [2]	Under Investigation by firm
Action	Depuy Orthopaedics initiated a recall on October 25, 2016. Notices were sent to the US Distributors via email on October 25, 2016. Customers were instructed to do the following: 1. Immediately Inspect Inventory, 2. Immediately Return US Distributor Inventory: If any affected instruments are found in a US Distributors inventory, return to: DePuy Synthes Joint Reconstruction, a division of DePuy Orthopaedics, Inc. 3. To expedite the return and credit process: Be sure to reference H16-14 on all return paperwork and/or online return forms and on the outside of the box when returning recalled lots of the instrument. 4. Upon receipt of the affected instruments, affected instruments will be credited against the US Distributors B&R budget. 5. Within 5-Business Days: Complete the Distributor Card or for the Reconciliation Form: Within 5-business days of initiation, the completed Reconciliation Form should be returned to DePuy Orthopaedics, Inc. 6. Retain copies of all field action documents in customer files For further questions please call (574) 371-4917.
Quantity in Commerce	137