Class 2 Device Recall Biomet Integral Centralizer Hip System

See Related Information 22

Date Posted	January 13, 2016
Recall Status[1]	Open
Recall Number	Z-0650-2016
Recall Event ID	72521[23]
510(K)Number	K942479[24]
Product Classification	Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented[25] - **Product Code** LZO[26]
Product	Biomet Integral Centralizer Hip System, Lateralized Femoral Stem (Co-Cr-Mo), 9mm, 11mm, 13mm, 15mm, and 17mm
Code Information	Part #11-162709 9mm Lots: 329750, 404380, 487400, 767120, 951680 Part # 11-162711 11mm Lots: 329760, 505030, 505050 Part # 11-162713 13mm Lots: 837750, 977460 Part # 11-162715 15mm 772410, 837780, 897070, 951810 Part # 11-162717 17mm Lots: 311410, 410500, 535530, 712800, 728080, 829580
Recalling Firm/ Manufacturer	Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	Audrey Daenzer 574-372-1570
Manufacturer Reason for Recall	PMMA is listed as a material on the label but the product does not contain PMMA.
FDA Determined Cause [2]	Labeling Change Control
Action	On 11/17/2015, URGENT MEDICAL DEVICE RECALL NOTICE notifications were sent to the affected distributors via courier with instructions for identifying and returning the affected product. The recall notification included a description of the reason for the recall, affected