Class 1 Recall
Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology

See Related Information[23]

Date Posted	June 08, 2015
Recall Status[1]	Open
Recall Number	Z-1699-2015
Recall Event ID	71272[24]
Premarket Notification 510(K) Number	K071856[25]
Product Classification	Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component)[26] - **Product Code** KWA[27]
Product	M/L Taper with Kinectiv® Technology. prosthesis, hip, semi-constrained (metal uncemented acetabular component) Product Usage: Usage: Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.
Code Information	Product: 00771300500 Lots: 63006851 63006852 63024180 Product: 00771300600 Lots: 63024183 63024184 63024186 63024187 63024188 63024189 Product: 00771300700 Lots: 63024193 63024195 63024196 63024197 63024198 63024199 63024201 63024202 63024203 63024204 63024205 63024206 Product: 00771300900 Lots: 62927082 62927083 63024210 63024211 63024213 63024214 63024215 63024216 63024217 63024218 63024219 63024220 63024221 Product: 00771301000 Lots: 62938997 63024226 63024227 63024228 63024229 63024230 Product: 00771301100 Lots: 62885040 62905574 62998426 63024234 63024235 63024236 63024237 63024238 63024239 63024240 63024241 Product: 00771301200 Lots: 62927123 63024256 63024257 63024258 63024259 63024261 63024262 63024263 Product: 00771301300 Lots: 62885058 62939008 63024245 Product: 00784801400 Lot: 62924878 Product: 65771301100 Lot: 62939041
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
For Additional Information Contact	Consumer Relations Call Center 877-946-2761
Manufacturer Reason for Recall	Zimmer is initiating a voluntary recall of 64 lots (752 implants total) of M/L Taper with Kinectiv¿ femoral stems and modular necks due higher than allowed cytotoxicity levels found with the product. Reasonable probability of adverse biological response and subsequent revision
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Zimmer, Inc. sent an URGENT MEDICAL DEVICE RECALL letter dated May 18, 2015, to all affected consignees. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. Customers were instructed to review the notification and ensure affected