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

	personnel are aware of the contents. Locate all affected product identified and quarantine them immediately. Carry out a physical count of all affected product in their inventory and complete the Inventory Return Certification Form. Email a completed copy to corporatequality.postmarket@zimmer.com. Return the recalled product along with the completed Inventory return Certification Form. Notify Zimmer of any hospitals that they have further distributed the affected product to. In addition, identify the surgeons that have implanted the product. Supply the information for any hospitals that they have identified, as well as the affected surgeons using the provided spreadsheet template. Customers with questions or concerns should call the customer call center at 1-877-946-2761.
Quantity in Commerce	752
Distribution	Worldwide Distribution - US Nationwide in the states of AK, AL, AZ, CA, FL, GA, IL, IN, KS, MA, MI, MN, MO, NC, NY, OH, OK, PA, TX, UT, VA, WA, WI and countries of Canada, Australia, Japan, Taiwan, France, Germany, Spain, and Italy.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = KWA and Original Applicant = ZIMMER, INC.[30]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
23. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
24. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71272
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K071856
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KWA