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

Date Posted: June 08, 2015
Recall Status: Open
Recall Number: Z-1699-2015
Recall Event ID: 71272
Premarket Notification 510(K) Number: K071856
Product Classification: Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component) - Product Code KWA

Product: M/L Taper with Kinetic® 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, poliomyelitis, 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.


Recalling Firm/Manufacturer: Zimmer, Inc.
1800 W Center St
Warsoaw, 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 Kinetic® 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: 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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=137182
6/24/2015
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 1-877-948-2761.

**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

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55.

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.

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Links on this page:

4. http://www.fda.gov/MedicalDevices/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/cfCla/Retrieve.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
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