Class 2 Recall Zimmer

See Related Information[23]

Date Posted	February 27, 2015
Recall Status[1]	Open
Recall Number	Z-1219-2015
Recall Event ID	70500[24]
Premarket Notification 510(K) Number	K101296[25]
Product Classification	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented[26] - **Product Code** LZO[27]
Product	Zimmer Segmental System (ZSS) Cemented Stem / ZSS Cemented Stem, Smooth Stem Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented.
Code Information	Item No. 00-5852-052-10; Lot 62866438
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
For Additional Information Contact	Consumer Relations Call Center 800-447-5633
Manufacturer Reason for Recall	PMMA coating does not meet specifications. If the stem is used in surgery, the most probable outcome is that no injuries would occur as the area missing PMMA coating has surface characteristics that would be sufficient to bond with bone cement. If injury did occur, it would be noted by patient pain due to loosening and subsequent loss of ROM precipitating a revision surgery. Surgeons who are expe
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Zimmer sent an URGENT MEDICAL DEVICE RECALL - Lot Specific letter dated February 5, 2015, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Your Responsibilities 1. Review the notification and ensure affected personnel are aware of the contents. 2. Locate and remove from inventory the affected products identified above. 3. Return any affected product with missing PMMA coating per the PER process 4. Return the Notification Acknowledgment Form (Attachment 1) to corporatequality.postmarket@zimmer.com. 5. Please notify Zimmer if the hospital that you have distributed the affected product to has implanted the product. In addition, identify the surgeons that have used this product. 6. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-276[illegible] between 8:00 am and 5:00pm EST.
Quantity in Commerce	1 unit
Distribution	US Distribution to the state of TX
Total Product Life Cycle	TPLC Device Report[28]