Class 2 Recall Stryker Orthopaedics

See Related Information[23]

Date Posted	May 19, 2015
Recall Status[1]	Open
Recall Number	Z-1633-2015
Recall Event ID	70994[24]
Premarket Notification 510(K) Number	K102019[25]
Product Classification	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented[26] - **Product Code** LPH[27]
Product	Stryker Howmedica Osteonics RESTORATION Acetabular Augment System; Howmedica Osteonics Corp., A subsidiary of Stryker Corporation Made in USA Sterile. Hip prosthesis component. The RESTORATION Acetabular Wedge Augments provide multiple options to address the wide range of bone deficiencies encountered in acetabular revision. The augments provide support for the shell in the acetabulum with superior and/or posterior defects.
Code Information	Ref #:Lot Number - 5096-4615:MMR8M8; 5096-4615:MMRLYD; 5096-4615:MNAYT7; 5096-5015:MMPO6K; 5096-5015:MMRWOJ; 5096-5015:MNADVA; 5096-5815:MNA40L; 5096-5820:MMR6HX; 5096-5825:MMRLD7; 5096-6225:MMPWO5; 5096-6225:MMRM2Y; 5096-6625:MMNM07
Recalling Firm/ Manufacturer	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah, New Jersey 07430-2006
For Additional Information Contact	Mr. Paul Jahnke 201-831-5826
Manufacturer Reason for Recall	Stryker Orthopaedics initiated a voluntary product recall for specific lots of Triathlon Femoral, Scorpio Femoral, Restoration Wedge Augments distributed from their Mahwah Manufacturing Facility. It was found that the peel strength of the inner blister may have been below internal validated requirements. The strength of the seal is directly related to long term shelf life of the sterile barrier.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	The firm, Stryker Orthopaedics, notified their Branches/Agencies via email on 8/15/2014 and sent an "Urgent Product Recall" letter dated 8/15/2014 with a Product Recall Acknowledgement Forms to their Branches/Agencies and consignees. The letter describes the product, issue, potential hazards and actions to be taken. The consignees were instructed to complete and return the attached Product Recall Acknowledgment Form within 5 days via fax to 855-251-3635; and return the affected product to the attention of Regulatory Compliance, Stryker Orthopaedics, 325 Corporate Drive, Mahwah NJ 07430. If you have any questions, feel free to contact Sr. Regulatory Compliance Specialist to 201-831-5826.
Quantity in Commerce	1,147 in total
Distribution	Worldwide Distribution: US (nationwide) including PR and countries of: Australia, Canada,