Class 2 Device Recall LIMA Modular Revision Hip Stem

See Related Information 22

Date Initiated by Firm	January 10, 2017
Create Date	February 11, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1191-2017
Recall Event ID	76209[23]
510(K)Number	K092331[24]
Product Classification	Prosthesis, hip, semi-constrained (metal uncemented acetabular component)[25] - **Product Code** KWA[26]
Product	LIMA Modular Revision Hip Stem Model 428-01-050_110 Product Usage: The Modular Revision Femoral hip stem is made up of a modular stem coupled with a proper neck by means of a Morse taper stabilized during the implantation phase by a safety screw. This system is particularly indicated for revision surgery on both uncemented and cemented femoral implants, when there is significant bone loss and an abnormal meta-epiphyseal anatomy of the femur.
Code Information	1005528A, 1006882A, 1107305A, 1101798A, 1100565A, 1005531A, 1211716A, 1007408A, 1004038B, 1005533D, 1106805A, 1203471A, 1005533C, 1100565A, 1101795A, 1007079A, 1005532A, 1100560A
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional Information Contact	Desiree Wells 512-832-9500
Manufacturer Reason for Recall	Lima Proximal Bodies were inadvertently re-sterilized. The safety screw which affixes the distal and proximal bodies of the stem includes a thread-locking plug made from UHMWPE, which is not approved for repeated gamma sterilization.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	DJO Global sent an Urgent Field Safety Notice letter dated January 10, 2017 to customers. The letter identified the affected product, problem and actions to be taken. Customers were asked to complete the Acknowledgement and receipt Form. Customers were instructed to contact Customer Service at 1-800-456-8696 to explore options for a replacement order.
Quantity in Commerce	13 devices
Distribution	US Nationwide - US Nationwide in the states of MS, OH, RI, NY, OK, TX, CA, HI
Total Product Life Cycle	TPLC Device Report[27]