## Class 2 Device Recall LIMA Modular Revision Hip Stem

### Date Initiated by Firm
January 10, 2017

### Create Date
February 11, 2017

### Recall Status
Open, Classified

### Recall Number
Z-1191-2017

### Recall Event ID
76209

### 510(K) Number
K092331

### Product Classification
Prosthesis, hip, semi-constrained (metal uncemented acetabular component) - Product Code KWA

### 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

### 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
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

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=152523

2/20/2017