FDA

Class 2 Device Recall Exprt Precision System

See Related Information[22]

Date Initiated by Firm	September 21, 2018
Create Date	April 10, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1123-2019
Recall Event ID	82379[23]
510(K)Number	K163497[24]
Product Classification	Prosthesis, hip, constrained, cemented or uncemented, metal/polymer[25] - **Product Code** KWZ[26]
Product	Exprt Precision System: Revision Hip, Proximal Body with Bolt, Lateral Offset, Sterile R, djo surgical, REF: 495-00-065, 495-00-075, 495-00-085, 495-01-065, 495-01-075, 495-01-085
Code Information	All lots.
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional Information Contact	512-832-9500
Manufacturer Reason for Recall	Complaints regarding loose proximal body bolts or bolts that were found through x-ray as sitting above the proximal body and not properly seated. Patient risks may include: pain, dissociation, and possible revision surgery
FDA Determined Cause [2]	Other
Action	On 09/21/18, Urgent Field Safety Notices, updated surgical techniques, and Acknowledgement and Receipt Forms were emailed to Surgical Sales Agents. The Surgical Technique provides instructions on use of the manual T-handle as the primary tightening method. It also provides instructions for use of the torque wrench to ensure that the readout for the torque wrench is at "0" before torque is applied. Sales agents were asked to affirm that they have read and understood the updated Surgical Technique information provided in the Field Safety Notice Bulletin. They were also asked to affirm that they disseminated this information to all employed and contracted sales reps in their organization. On 01/29/19, Urgent Field Safety Notices were emailed to Surgical Agents. This notice communicated the exchange process for physical product in inventory. The firm will notify Surgical Agents to make arrangements for the exchange of affected inventory with proximal bodies that are