See Related Information[22]

Class 2 Device Recall EMPOWR Porous Knee System TIBIAL PUNCH, LARGE

Date Initiated by Firm	December 12, 2017
Create Date	January 10, 2018
Recall Status[1]	Completed
Recall Number	Z-0329-2018
Recall Event ID	78727[23]
510(K)Number	K100900[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26]
Product	EMPOWR Porous Knee System TIBIAL PUNCH, LARGE, REF 801-05-204, NON STERILE, Qty 1 For use in orthopedic surgery.
Code Information	Lot 252564
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional Information Contact	512-832-9500
Manufacturer Reason for Recall	The Locking Punch Guide was not sufficiently guiding the large press fit punch, causing the implant to be placed 2-3mm more posterior than intended.
FDA Determined Cause [2]	Device Design
Action	The field safety notice was disseminated by email on 12/12/2017. The notice stated the following: "DJO Sales Agents Action: Please review the bulletin that is provided with this notice. This bulletin contains new instructions on the use of the Locking Punch Guide and Punch. Please ensure your surgeons are familiar with this information. DJO Surgical then requires that you complete the attached acknowledgment and email it to teffany.hutto@djoglobal.com. Please have this form returned by December 15, 2017 Once redesigned guides are available, they will be exchanged through a separate field action."
Quantity in Commerce	2 units
Distribution	One medical device distributor in California.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.