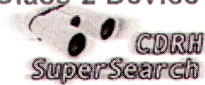




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**Class 2 Device Recall EMPOWR Porous Knee System TIBIAL PUNCH, LARGE**

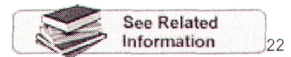


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>7</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

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



<b>Date Initiated by Firm</b>	December 12, 2017
<b>Create Date</b>	January 10, 2018
<b>Recall Status<sup>1</sup></b>	Completed
<b>Recall Number</b>	Z-0329-2018
<b>Recall Event ID</b>	<a href="#">78727</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K100900</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer</a> <sup>25</sup> - <b>Product Code</b> <a href="#">JWH</a> <sup>26</sup>
<b>Product</b>	EMPOWR Porous Knee System TIBIAL PUNCH, LARGE, REF 801-05-204, NON STERILE, Qty 1 For use in orthopedic surgery.
<b>Code Information</b>	Lot 252564
<b>Recalling Firm/Manufacturer</b>	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
<b>For Additional Information Contact</b>	512-832-9500
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Device Design
<b>Action</b>	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 <a href="mailto:teffany.hutto@djoglobal.com">teffany.hutto@djoglobal.com</a> . Please have this form returned by December 15, 2017 Once redesigned guides are available, they will be exchanged through a separate field action."
<b>Quantity in Commerce</b>	2 units
<b>Distribution</b>	One medical device distributor in California.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.