



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

### Class 2 Device Recall NexGen LPS

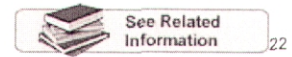


[6 510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [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>

[New Search](#)

[Back to Search Results](#)

### Class 2 Device Recall NexGen LPS



|   |   |
|---|---|
| <b>Date Initiated by Firm</b>             | July 24, 2017   |
| <b>Create Date</b>                        | February 21, 2018   |
| <b>Recall Status<sup>1</sup></b>          | Open <sup>3</sup> , Classified  |
| <b>Recall Number</b>                      | Z-0663-2018   |
| <b>Recall Event ID</b>                    | <a href="#">78960</a> <sup>23</sup>   |
| <b>PMA Number</b>                         | <a href="#">P060037</a> <sup>24</sup>   |
| <b>Product Classification</b>             | <a href="#">Prosthesis, knee, patellofemorotibial, semi-constrained, metal/polymer, mobile bearing</a> <sup>25</sup> - <a href="#">Product Code NJL</a> <sup>26</sup>   |
| <b>Product</b>                            | NexGen LPS Femoral Component, Left and Right, Size G<br><br>Replaces the femoral condyle of the knee joint in Total Knee Arthroplasty.  |
| <b>Code Information</b>                   | Item Number: 00-5964-017-51, Lot Numbers (UDI Number): 63329529 ((01) 00889024001152 (17) 260430 (10) 63329529); 63342472 ((01) 00889024001152 (17) 260430 (10) 63342472); 63329533 ((01) 00889024001152 (17) 260430 (10) 63329533); 63329527 ((01) 00889024001152 (17) 260430 (10) 63329527)   |
| <b>Recalling Firm/Manufacturer</b>        | ZIMMER ORTHOPEDIC MFG LTD<br>Building No 2 East Park<br>Shannon Industrial Estate<br>Shannon Ireland  |
| <b>For Additional Information Contact</b> | 800-613-6131  |
| <b>Manufacturer Reason for Recall</b>     | There is a possibility that the protective foam insert used during the packaging of the affected products is undersized, which may cause a breach in the inner cavity during transportation.  |
| <b>FDA Determined Cause<sup>2</sup></b>   | Reprocessing Controls   |
| <b>Action</b>                             | On approximately July 24, 2017, customers were notified via letter of the recall. Instructions for distributors included to ensure affected personnel are aware of the recall, locate and quarantine any affected product in inventory, complete and return the Inventory Return Certification Form, make arrangements to return the product Zimmer Biomet, and provide customers if product was further distributed. Instructions for Risk Managers at medical facilities include to ensure affected personnel are aware of the recall, to assist the Zimmer Biomet sales representative in identifying and quarantining affected devices so they can be removed by the sales representative, and to complete and return the Certification of Acknowledgement form. Further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. or 1 (800) 613-6131 |
| <b>Quantity in Commerce</b>               | 7 devices   |
| <b>Distribution</b>                       | Worldwide Distribution - US Distribution to the states of : CA, MA, ME, MI, MN and WI., and   |