Class 2 Device Recall NexGen LPS

See Related Information[22]

Date Initiated by Firm	July 24, 2017
Create Date	February 21, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0663-2018
Recall Event ID	78960[23]
PMA Number	P060037[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, metal/polymer, mobile bearing[25] - **Product Code** NJL[26]
Product	NexGen LPS Femoral Component, Left and Right, Size G Replaces the femoral condyle of the knee joint in Total Knee Arthroplasty.
Code Information	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)
Recalling Firm/ Manufacturer	ZIMMER ORTHOPEDIC MFG LTD Building No 2 East Park Shannon Industrial Estate Shannon Ireland
For Additional Information Contact	800-613-6131
Manufacturer Reason for Recall	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.
FDA Determined Cause [2]	Reprocessing Controls
Action	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
Quantity in Commerce	7 devices
Distribution	Worldwide Distribution - US Distribution to the states of : CA, MA, ME, MI, MN and WI., and