Class 2 Device Recall DROP LOK" Knee Brace

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Class 2 Recall
DROP LOK" Knee Brace See Related Information[21]

Date Posted	May 10, 2014
Recall Status[1]	Open
Recall Number	Z-1603-2014
Recall Event ID	68017[22]
Product Classification	Stocking, Medical Support (To Prevent Pooling Of Blood In Legs)[23] - **Product Code** DWL[24]
Product	DROP LOK" Knee Brace***LATEX FREE" Product Usage: Used in the treatment, support, and rehabilitation of many types of knee injuries or following surgical correction.
Code Information	Model #: 00-1746-001-00 through 00-1746-006-00
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	During a transfer of products from a recently shutdown facility, the firm discovered raw material labeled as latex free actually contained latex.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Labeling Mix-Ups
Action	Zimmer sent an Urgent: Device Removal Letters dated April 8, 2014 to their customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to review this notification, identify and quarantine the affected product to prevent further distribution or use, complete the attached Response Form and return it via email. orporateQuality_PostMarket@zimmer.com. Return affected product to: Zimmer Surgical Attn: QA/RA Dept.- Recall 200 West Ohio Avenue Dover, Ohio 44622 USA Please include a copy of the Response Form with the shipment. For returns outside the US, please email Rhonda.duncan@zimmer.com obtain an IRA (international return authorization) number. The IRA request should include the part number(s) being returned and the quantity. Please write the associated IRA number on the outside of the box. 4. Zimmer will credit your account for returned Drop-Lok" Knee Braces, Cartilage Knee Braces, Hinged Knee Supports, or Neoprene Tennis Elbow Supports. Please return a copy of the completed response form along with your returned product to ensure proper credit. Important: Please distribute this notification to all personnel within your organization who need to be aware. If you have further transferred affected product(s), please provide the customer's information on the Business Response Form to Zimmer. For questions call 330-354-0989.
Quantity in Commerce	131 units
Distribution	Worldwide Distribution - US Nationwide in the states of: AK, AZ, CA, FL, GA, IA, IL, IN, LA, MD, MI, MO NC, NE, NV, NY, OH, OK, OR, PA, RI, SD, TX, UT, VA, VT, WA, WI & WV and countries of: AUSTRALIA, CANADA, GERMANY, IRAQ, ITALY, SAUDI ARABIA, TUNISIA & UNITES ARAB EMIRATES.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Class 2 Recall Cartilage Knee Brace

See Related Information[21]

Date Posted	May 10, 2014
Recall Status[1]	Open
Recall Number	Z-1604-2014
Recall Event ID	68017[22]
Product Classification	Stocking, Medical Support (To Prevent Pooling Of Blood In Legs)[23] - **Product Code** DWL[24]
Product	Cartilage Knee Brace***LATEX FREE" Product Usage: Used in the treatment and support of many types of knee injuries or following surgical and nonsurgical correction.
Code Information	Model #: 00-1747-001-00 through 00-1747-005-00
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	During a transfer of products from a recently shutdown facility, the firm discovered raw material labeled as latex free actually contained latex.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Labeling Mix-Ups
Action	Zimmer sent an Urgent: Device Removal Letters dated April 8, 2014 to their customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to review this notification, identify and quarantine the affected product to prevent further distribution or use, complete the attached Response Form and return it via email. orporateQuality_PostMarket@zimmer.com. Return affected product to: Zimmer Surgical Attn: QA/RA Dept.- Recall 200 West Ohio Avenue Dover, Ohio 44622 USA Please include a copy of the Response Form with the shipment. For returns outside the US, please email Rhonda.duncan@zimmer.com obtain an IRA (international return authorization) number. The IRA request should include the part number(s) being returned and the quantity. Please write the associated IRA number on the outside of the box. 4. Zimmer will credit your account for returned Drop-Lok" Knee Braces, Cartilage Knee Braces, Hinged Knee Supports, or Neoprene Tennis Elbow Supports. Please return a copy of the completed response form along with your returned product to ensure proper credit. Important: Please distribute this notification to all personnel within your organization who need to be aware. If you have further transferred affected product(s), please provide the customer's information on the Business Response Form to Zimmer. For questions call 330-354-0989.
Quantity in Commerce	2,222 units
Distribution	Worldwide Distribution - US Nationwide in the states of: AK, AZ, CA, FL, GA, IA, IL, IN, LA, MD, MI, MO NC, NE, NV, NY. OH, OK, OR, PA, RI, SD, TX, UT, VA, VT, WA, WI & WV and countries of: AUSTRALIA, CANADA, GERMANY, IRAQ, ITALY, SAUDI ARABIA, TUNISIA & UNITES ARAB EMIRATES.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
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