Class 2 Device Recall Bone Cement

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See Related Information[22]

Recall Date	August 19, 2016
Recall Status[1]	Open
Recall Number	Z-2606-2016
Recall Event ID	74800[23]
510(K)Number	K051496[24]
Product Classification	Bone cement[25] - **Product Code** LOD[26]
Product	Cobalt HV Bone Cement Product Usage: Cobalt HV Bone Cement provides two separate, pre-measured and sterilized components which when mixed form a radiopaque, rapidly setting bone cement.
Code Information	Lot 507970
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional Information Contact	Desiree Wells 512-832-9500
Manufacturer Reason for Recall	The outer packaging was mislabeled on the box indicating "Cobalt HV with Gentamicin". The bone cement does not contain antibiotics.
FDA Determined Cause [2]	Labeling mix-ups
Action	The recalling firm sent an Urgent Field Safety Notice letter dated July 26 2016 to Sales Agents. The letter identified the affected product, problem and actions to be taken. The sales agents were instructed to pass on the notice to any organization where the potential affected product has been transferred. Agents were instructed to identify hospitals in their territory, complete a visually inspection of the affected product in the hospital's inventory, complete an Acknowledgement and Receipt form. If affected products is found contact Customer Service at 1-800-456-8696 for replacement.
Quantity in Commerce	866 units
Distribution	US Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = LOD and Original Applicant = BIOMET, INC.[29]

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