Class 2 Recall AlloFuse DBM Putty 5cc See Related Information[21]

Date Posted	May 06, 2014
Recall Status[1]	Open
Recall Number	Z-1562-2014
Recall Event ID	67986[22]
Premarket Notification 510(K) Number	K071849[23]
Product Classification	Filler, Bone Void, Calcium Compound[24] - **Product Code** MQV[25]
Product	AlloFuse DBM Putty 5cc, Catalog No. 90038005 AlloFuse is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. AlloFuse is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender.
Code Information	Lot numbers 132095-603, 608, 609, 611-618, 622-629, 631-634, and 636-638. Lot numbers 132095-604, 619, and 621.
Recalling Firm/ Manufacturer	AlloSource, Inc. 6278 S Troy Cir Centennial, Colorado 80111-6422
For Additional Information Contact	Trevor Wright 720-873-4733
Manufacturer Reason for Recall	The donor was hemodiluted.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	AlloSource sent letter via USPS Certified Mail Receipt to all affected customers dated March 25, 2014, and March 26, 2014. The letter identified the product the problem and the action needed to be taken by the customer. AlloSource requested that the distributor consignee notify subsequent consignees to determine disposition and to request return of unused product. Returned inventory will be quarantined physically and electronically upon receipt. Product initially quarantined and product returned will be destroyed following established procedures. Further questions please call (720) 873-4733.
Quantity in Commerce	29
Distribution	Distribution US nationwide, including Michigan and a distributor in Colorado.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[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 = MQV and Original Applicant = ALLOSOURCE, INC.[28]

Links on this page: