Class 2 Device Recall AlloFuse DBM Putty 5cc

Date Posted: May 06, 2014
Recall Status: Open
Recall Number: Z-1562-2014
Recall Event ID: 67066222
Premarket Notification 510(K) Number: K07164923
Product Classification: Filler, Bone Void, Calcium Compound - Product Code MQV
Product: AlloFuse DBM Putty 5cc, Catalog No. 90039005 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.
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 hemolyzed.
FDA Determined Cause: 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

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

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