Class 2 Device Recall Regenerex Patella

See Related Information[22]

Date Initiated by Firm	March 22, 2017
Date Posted	April 25, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2068-2017
Recall Event ID	77094[23]
510(K)Number	K083782[24]
Product Classification	Prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/[25] - **Product Code** MBH[26]
Product	Regenerex Patella RGX 3 PEG SER A PATELLA 28MM RGX 3 PEG SER A PATELLA 31MM RGX 3 PEG SER A PATELLA 34MM RGX 3 PEG SER A PATELLA 37MM Product Usage: The Regenerex Series A Patella can be used for any non-cemented resurfaced 3-peg patella application within the Vanguard Complete Knee System. 1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.
Code Information	All lots of Model #'s: , 141355, 141356, 141357, 141358
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	pegs shearing post-operatively
FDA Determined Cause [2]	Under Investigation by firm
Action	On 3/22/2017 URGENT MEDICAL DEVICE RECALL REMOVAL notifications were sent to the affected consignees via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. Distributors, Sales Representatives, and Distributor Operation Managers Your Responsibilities 1. Review this notification and ensure affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in your inventory. 3. Complete the Certification of Acknowledgement portion of Attachment 1 Inventory Return Certification Form. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. 4. Immediately return all affected product from your distributorship and affected hospitals within your territory along

	with a completed Attachment 1 Inventory Return Certification Form to Zimmer Biomet. a. Request a Return Authorization Number via email to rgarequest@zimmerbiomet.com or through FAST/SMS. Be sure to specify RECALL as the RGA type when requesting. b. For each return, send a copy of Attachment 1 to corporatequality.postmarket@zimmerbiomet.com. c. Include a hardcopy of Attachment 1 with your shipment for immediate processing. d. Mark the outside of the returns box(es) clearly with RECALL. 5. Note that any hospitals and surgeons that received direct shipments of this product from Zimmer Biomet or were consigned products, will be sent a copy of the Risk Manager and Surgeon Field Action Notice directly. It is important that you review the list of hospitals and surgeons included with the email notification sent to your facility to identify additional accounts Zimmer Biomet has not notified. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any additional hospitals and/or surgeons that may hav
Quantity in Commerce	8154
Distribution	US Nationwide.distribution and Canada.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = MBH and Original Applicant = BIOMET MANUFACTURING CORP.[29]

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