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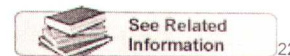
Class 2 Device Recall Comprehensive Shoulder System

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Class 2 Device Recall Comprehensive Shoulder System



Date Initiated by Firm	October 10, 2018
Create Date	December 07, 2018
Recall Status¹	Open ³ , Classified
Recall Number	Z-0591-2019
Recall Event ID	81528 ²³
510(K)Number	<u>K060692</u> ²⁴
Product Classification	Prosthesis, shoulder, semi-constrained, metal/polymer, uncemented ²⁵ - Product Code MBF ²⁶
Product	Comprehensive Mini Stem, Item No. 113631:
Code Information	568150
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	Zimmer Biomet is conducting a lot specific medical device recall for two lots of the Orthopedic Salvage System (OSS) and the Comprehensive Shoulder System. The investigation determined that the Mini Humeral Stem is potentially labeled as the Bowed IM Stem lot. The associated risk of this product issue is a potential extension of surgery <30 minutes if a replacement is readily available.
FDA Determined Cause²	Under Investigation by firm
Action	On October 10, 2018, the firm notified affected customers via Urgent Medical Device Recall letters. Customers were advised of the product issue. Distributors were asked to take the following actions: 1. Review this notification and ensure that affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in your inventory. 3. If the affected product is located at a hospital, remove the product from the hospital and provide the Risk Manager Recall Notice to the hospital and request that they sign the Certificate of Acknowledgement. 4. Immediately return all affected product from your distributorship and from affected hospitals within your territory along with hospital Certificate of Acknowledgement. a. For each return, complete Attachment 1 Inventory Return Certification Form and send to CorporateQuality.PostMarket@zimmerbiomet.com within three (3) days. b. For each return, send a copy of Attachment 1 to CorporateQuality.PostMarket@zimmerbiomet.com. c. Include a hardcopy of Attachment 1 in each carton of your return shipment for immediate processing. d. Mark RECALL on the