FDA

Class 2 Device Recall ECHO BiMetric Hip System

See Related Information[22]

Date Initiated by Firm	June 08, 2018
Create Date	August 14, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2821-2018
Recall Event ID	80534[23]
510(K)Number	K070274[24]
Product Classification	*Prosthesis, hip, semi-constrained (metal uncemented acetabular component)*[25] - **Product Code** KWA[26]
Product	ECHO Bi-Metric Hip System, Reduced Proximal Profile, Standard 135o neck, item number 192414. orthopedic hip prosthesis femoral stem
Code Information	lot 944680. UDI (01)00880304463370(17)280206(10)944680
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	Customer Service 574-371-3071
Manufacturer Reason for Recall	Two lots of the Echo Bi-Metric Hip Stem and ARCOS Modular Revision Hip Stem may have been comingled. Potential health consequences include extension of surgery time to find a replacement component.
FDA Determined Cause [2]	Process control
Action	The firm sent an initial email on June 6, 2018, to US distributors that received affected product. Distributors were asked to quarantine any affected product on hand. The formal recall notice was then prepared and emailed to distributors on June 8, 2018. On the same day, hospital risk managers and distributors received notification via courier. " The distributors notice identified the issue and their responsibilities. These responsibilities included locating and removing the product in their territory, as well as identifying hospitals who have previously used the product. " Distributors will return on-hand product to Zimmer Biomet and ensure all of their products are accounted for using the form provided in the letter. " The hospital risk manager notice identified the issue and their responsibilities. These responsibilities include: - Assisting the Zimmer Biomet sales representative with the quarantine of the product - Returning Certificate of Acknowledgement to Zimmer Biomet. If you have further questions or concerns after reviewing this information, please call Zimmer Biomet customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.
Quantity in Commerce	12