Class 2 Device Recall Vanguard Knee

See Related Information[22]

Date Initiated by Firm	December 15, 2016
Create Date	February 16, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1219-2017
Recall Event ID	76178[23]
510(K)Number	K142933[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26]
Product	Vanguard Total Knee, PUNCH THRU TRL PLATES, 63 MM Item No: 32-487261, 67 MM Item No: 32-487262, 71 MM Item No: 32-487263, 75 MM Item No: 32-487264, and 79 MM Item No: 32-487265
Code Information	Vanguard Total Knee, PUNCH THRU TRL PLATES, 63 MM Item No: 32-487261, 67 MM Item No: 32-487262, 71 MM Item No: 32-487263, 75 MM Item No: 32-487264, and 79 MM Item No: 32-487265; Lot No's: ZB160701, ZB160702, ZB160703, ZB160701, ZB160702, ZB160701, ZB160702, ZB160703, ZB160801, ZB160802, ZB160803, ZB160801, ZB160802.
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	Customer Service 800-348-2759
Manufacturer Reason for Recall	Zimmer Biomet is conducting a medical device recall for ARCOS & TPRLC broaches and rasps due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.
FDA Determined Cause [2]	Material/Component Contamination
Action	Zimmer Biomet is conducting a medical device recall for ARCOS & TPRLC broaches and rasps due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument
Quantity in Commerce	26
Distribution	Domestic: 0 Foreign: Singapore & Malaysia
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.