FDA

Class 2 Device Recall TITAN

See Related Information[22]

Date Initiated by Firm	December 20, 2017
Create Date	April 20, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1463-2018
Recall Event ID	79597[23]
Product Classification	Template[24] - **Product Code** HWT[25]
Product	The humeral stems trials are packaged in a kit for Titan Modular Shoulder System. Each kit contains 1 of each size. The kit components are packaged in individual corrugated cardboard boxes. Kits are then packaged as a case pack in cardboard boxes. *This product is used for off-loading diabetic foot ulcer.*
Code Information	See Consignee List.
Recalling Firm/ Manufacturer	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344
For Additional Information Contact	609-275-0500
Manufacturer Reason for Recall	Incidents of stem trial breakage were reported to the firm suggesting that these fractures all occurred during insertion/impaction or extraction of the humeral stem trial whiling preparing the humeral canal and/or trialing. All cases resulted in a delay in surgery, with a variance of medical intervention required.
FDA Determined Cause [2]	Device Design
Action	Firm sent letters to consignees on December 20, 2017. Firm asked consignees to examine inventory and determine if consignee had affected product. Firm promised to send new stem trials along with a return shipping label. Firm asked to complete the Acknowledgment and Return Form and email or fax back to firm. For further questions, please call (609) 275-0500.
Quantity in Commerce	1619 units
Distribution	Worldwide Distribution - USA (nationwide) Distribution.
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[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