Date Initiated by Firm: December 20, 2017

Create Date: April 20, 2018

Recall Status: Open, Classified

Recall Number: Z-1463-2018

Recall Event ID: 79597

Product Classification: Template - Product Code HWT

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 while 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: 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 Acknowledgement 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

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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.

2 For 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