Class 2 Device Recall DRAD SelfTapping Locking Screw

Date Initiated by Firm: March 07, 2018
Date Posted: March 20, 2018
Recall Status: Open, Classified
Recall Number: Z-1317-2018
Recall Event ID: 79515
510(K) Number: K132296
Product Classification: Screw, fixation, bone - Product Code HWC
Code Information: Lot Number 17GM04522
Recalling Firm/Manufacturer: Smith & Nephew, Inc.
1450 E Brooks Rd
Memphis TN 38116-1804
For Additional Information Contact: David Snyder
978-749-1440
Manufacturer Reason for Recall: One lot of D-RAD Self-Tapping Locking Screws used with the Distal Radius Fracture Kit were machined out of specification. Screws measured over tolerance within the head thread form by 0.002-0.003 inch.
FDA Determined Cause: Under Investigation by firm
Action: The firm initiated their recall by letter and email on 03/07/2018. The firm requested return of the product.
Quantity in Commerce: 59 units
Distribution: US, Puerto Rico, Malaysia
Total Product Life Cycle: TPLC Device Report

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 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 updated as the status changes.

510(K) Database: 510(K)s with Product Code = HWC and Original Applicant = SMITH & NEPHEW, INC.