Class 2 Device Recall DRAD SelfTapping Locking Screw

See Related Information[22]

Date Initiated by Firm	March 07, 2018
Date Posted	March 20, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1317-2018
Recall Event ID	79515[23]
510(K)Number	K132296[24]
Product Classification	Screw, fixation, bone[25] - **Product Code** HWC[26]
Product	D-RAD Self-Tapping Locking Screw intended for the fixation of fractures involving the distal radius. smith&nephew D-RAD 2.4MM X 10MM S-T LOCKING SCREW, REF 74692410, QTY (1), STERILE R
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-Taping 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 [2]	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[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. Learn more about medical device recalls[28].
[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.[29]