See Related Information[22]

Class 2 Device Recall JOURNEY II XR TIBIAL POSTERIOR KEEL PUNCH SZ 34

Date Initiated by Firm	December 10, 2018
Create Date	March 22, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1043-2019
Recall Event ID	81766[23]
510(K)Number	K173331[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26]
Product	JOURNEY II XR TIBIAL POSTERIOR KEEL PUNCH SZ 3-4 , REF 74013987 The JOURNEY II XR Tibial Posterior Keel Punch is a reusable surgical instrument used to prepare the proximal tibial to receive a JOURNEY II XR tibial baseplate.
Code Information	Batch Numbers: 17JGA0021; 17JGA0021A; 17JGA0027; 17JGA0027A; 17JGA0027B; 17JGA0033A; 17JGA0033B; 17JGA0043; 17JGA0043A; 17JGA0043B; 17JGA0043R; 17JGA0047 & 18BGA0014B
Recalling Firm/ Manufacturer	Smith & Nephew, Inc. 1450 E Brooks Rd Memphis TN 38116-1804
For Additional Information Contact	Dave Snyder 978-749-1440
Manufacturer Reason for Recall	Higher than anticipated occurrence of bone fracture during the use of the XR Tibia Posterior Punch
FDA Determined Cause [2]	Device Design
Action	The firm, smith&nephew, initiated the recall by email with an "Urgent Medical Device Recall Notice" letter dated 12/10/18 to the customers on 12/10/2018. Letter describes the product, problem and actions to be taken. The customers were instructed to do the following: -Inspect your inventory and locate any devices from the listed product and batch numbers and quarantine them immediately. - If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out. -Complete and return the Response Form to FieldActions@smith-nephew.com or fax to 901-566-7975. Please Note even if you have no product to return, this form must be completed, signed and returned. If you have any questions or concerns regarding this recall please contact FieldActions@smith-