FDA

Class 2 Device Recall Titanium Trochanteric Fixation Nail (TFN)

See Related Information[22]

Date Initiated by Firm	July 21, 2017
Create Date	February 13, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0604-2018
Recall Event ID	78958[23]
510(K)Number	K011857[24]
Product Classification	Rod, fixation, intramedullary and accessories[25] - **Product Code** HSB[26]
Product	11MM/130 Degree Titanium Trochanteric Fixation Nail 380MM/Right, Sterile
Code Information	Lot H302839, Expiration Date 31Jan2026
Recalling Firm/ Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester PA 19380-5986
Manufacturer Reason for Recall	The locking mechanism and protective cap were missing from the sterile packed nails of the affected lot.
FDA Determined Cause [2]	Employee error
Action	The company issued a recall letter on 7/21/2017 asking customers to quarantine affected product and arrange for it to be returned.
Quantity in Commerce	4 units
Distribution	TX, GA, PA, UT and Canada
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 = HSB and Original Applicant = SYNTHES (USA)[29]

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