FDA Home> Medical Devices> Databases

Class 2 Device Recall Titanium Trochanteric Fixation Nail (TFN)

Date Initiated by Firm: July 21, 2017
Create Date: February 13, 2018
Recall Status: Open, Classified
Recall Number: Z-0604-2018
Recall Event ID: 7895823
510(K) Number: K01185724
Product Classification: Rod, fixation, intramedullary and accessories - Product Code HSB
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: 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 Report27

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 = HSB and Original Applicant = SYNTHES (USA)

Links on this page:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=160966 2/19/2018