Class 2 Device Recall Tritium Sternal Plate System

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See Related Information[21]

Date Posted	July 17, 2014
Recall Status[1]	Open
Recall Number	Z-2076-2014
Recall Event ID	68619[22]
Premarket Notification 510(K) Number	K133785[23]
Product Classification	Cerclage, Fixation[24] - **Product Code** JDQ[25]
Product	Tritium Sternal Plate System, Screw, 02.7mm X 12mm, 12 Pack, Sterile. The Pioneer Surgical Cable Plate System is used in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures. The screws are packaged as a 12 pack using a double tray packaging configuration.
Code Information	Model: 86-27-12-S12 UDI Number: 00846468061463 LOT: 168952 Expiration:12/23/2018
Recalling Firm/ Manufacturer	PIONEER SURGICAL TECHNOLOGY, INC. 375 River Park Cir Marquette, Michigan 49855-1781
For Additional Information Contact	Dan Nelson 906-226-4812
Manufacturer Reason for Recall	Lack of Sterility Assurance
FDA Determined Cause [2]	TRAINING: Employee Error
Action	On 6/11/14 and 6/12/14 the firm contacted their two consignees and surgeon via phone and explained that the product did not go through the sterilization process. The returns authorization number and shipping labels were discussed for the unused unit. On 6/18/14 and 6/20/14 an URGENT: MEDICAL DEVICE VOLUNTARY RECALL NOTIFICATION was sent to the customers as well as the one surgeon. The letter explained the sterility concerns and that the productis being recalled. Contact Dan Nelson, Manager of Quality, at 906-226-4489 if you have any questions or concerns.
Quantity in Commerce	5
Distribution	US Nationwide Distribution in the states of TX and FL
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = JDQ and Original Applicant = PIONEER SURGICAL TECHNOLOGY, INC[28]