Class 2 Device Recall

See Related Information[22]

Date Initiated by Firm	October 05, 2016
Create Date	November 16, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0592-2017
Recall Event ID	75337[23]
510(K)Number	K133221[24]
Product Classification	Orthosis, spinal pedicle fixation, for degenerative disc disease[25] - **Product Code** NKB[26]
Product	Arsenal Spinal Fixation System, Set Screw, Part No. 47127 Product Usage: Usage: The Arsenal Spinal Fixation System is intended for posterior, non-cervical, spinal fixation as an adjunct to fusion for the treatment of degenerative disease, deformity, and trauma indications. The Arsenal System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and bridges that provide temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The screws, hooks, connectors, and bridges are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI). The rods are available in commercially pure titanium, titanium alloy, and cobalt chrome (CP Ti Grade 4, Ti-6Al-4V ELI, and Co-28Cr-6Mo).
Code Information	Lot Numbers, 695621 , 696252 , 697128 , 698437 , 700943 , 7689801, 695622 , 696253 , 697129 , 698438 , 700944 , 7689802, 695623 , 696254 , 697130 , 698439 , 700945 , 7689803, 695624 , 696255 , 697131 , 698440 , 701393 , 7689804, 695625 , 696256 , 697520 , 698441 , 701394 , 695626 , 696257 , 697521 , 698442 , 701395 , 695627 , 696258 , 697522 , 700611 , 701396 , 696124 , 696558 , 697523 , 700612 , 701397 , 696125 , 696574 , 697524 , 700613 , 701398, 696126 , 696575 , 698433 , 700614 , 701399, 696127 , 696576 , 698434 , 700615 , 701400, 696128 , 696577 , 698435 , 700941 , 701401, 696251 , 697127 , 698436 , 700942 , 701851, 7878901, 7829602, 7766302, 7766301
Recalling Firm/ Manufacturer	Alphatec Spine, Inc. 5830 El Camino Real Carlsbad CA 92008-8816
For Additional Information Contact	760-431-9286
Manufacturer Reason for Recall	Alphatec Spine is recalling the Arsenal Spinal Fixation System Set Screw due to a trend in set screw postoperative disengagement from the screw body.
FDA Determined Cause [2]	Under Investigation by firm
Action	Alphatae Spine sent an Urgent Medical Device Recall notification letter dated September 29, 2016 to customers. The letter identified the affected product, problem and the actions to be taken. Customers are instructed to fill out and return the last page of recall letter using one of the methods identified in the letter.