

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		<small>DATE(S) OF INSPECTION</small> 4/3/2017-4/19/2017* <small>FEI NUMBER</small> 2027467					
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Michael J. Plunkett , President and Chief Operating Officer							
<small>FIRM NAME</small> Alphatec Spine, Inc.		<small>STREET ADDRESS</small> 5830 El Camino Real					
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Carlsbad, CA 92008-8816		<small>TYPE ESTABLISHMENT INSPECTED</small> Medical Device Manufacturer					
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p> <p><i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i></p> <p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Risk analysis is inadequate.</p> <p>Specifically,</p> <p>Your process for evaluating risks per your procedure Risk Management, Document Number: PRO-000003 is inadequate, in that:</p> <p>A design change to Arsenal Set Screw, Part Number 47027, was incorporated per CO-15111, dated 10/20/2014, based on market feedback during limited market release. The feedback was related to reported issues with initiating the set screw into the pedicle screw body. This change resulted in a part number change from Revision A to Revision B.</p> <p>Your risk assessment, Health Hazard Evaluation (HHE) Number 2015-003, dated 05/20/2015, was conducted to evaluate six complaints from January 2015 to May 2015, regarding Arsenal Set Screw, Part Number 47027, reports of set screw malfunction during intraoperative final tightening and complete disengagement from the screw body. The risk assessment determined that the risks associated with the failure modes were acceptable and no field action strategy was required, although MDR reportable events to include malfunctions (MDR Number 2027467-2015-00055 and MDR Number 2027467-2015-00075) and serious injury (MDR Number 2027467-2015-00074) had been observed.</p>							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Shaquenta Y Perkins, Investigator </td> <td style="width: 40%; vertical-align: top;"> <div style="text-align: right;"> <small>4/19/2017</small> DATE ISSUED 4/19/2017 </div> </td> </tr> <tr> <td colspan="2" style="text-align: right; padding-top: 10px;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;"> X Shaquenta Y Perkins <small>Shaquenta Y Perkins Investigator Signed by: Shaquenta Y. Perkins -S</small> </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Shaquenta Y Perkins, Investigator	<div style="text-align: right;"> <small>4/19/2017</small> DATE ISSUED 4/19/2017 </div>	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> X Shaquenta Y Perkins <small>Shaquenta Y Perkins Investigator Signed by: Shaquenta Y. Perkins -S</small> </div>	
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<p>Subsequently, HHE 2016-011, dated 08/02/2016 was conducted to evaluate a complaint trend due to set screw postoperative disengagement (back-out) from the screw body from October 2015 to August 2016 for set screw Part Number 47127, a later revision to Part Number 47027. The risk assessment stated that "Revision A of the set screw part number 47027 is identical in every way (except laser marking) to part number 47127. Revision B of the set screw part number 47027 makes minor dimensional changes thought to reduce cross threading and improve initial insertion. The Revision B color was changed (aqua anodized)..."</p> <p>It was noted that six additional complaints representing a total of sixteen set screws and six revision surgeries were also evaluated in risk assessment, HHE 2016-011, for set screw postoperative engagement from the screw body for Part Number 47027. Field action was deemed required and you performed correction and removal, Z-0592-2017, on 10/05/2016, for Part Number 47127, however, you did not extend the correction and removal to include the existing population in the field for Part Number 47027.</p> <p>According to the firm's field status reports, there are remaining set screws Part Number 47027 Revision A and Revision B currently in the market.</p>			
Annotations to Observations			
Observation 1: Promised to correct			
*DATES OF INSPECTION 4/03/2017(Mon),4/04/2017(Tue),4/05/2017(Wed),4/10/2017(Mon),4/12/2017(Wed),4/13/2017(Thu),4/19/2017(Wed)			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."