DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	01/20/2010 - 02/11/2010* FEI NUMBER 2027467

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kermit P. Stott, Vice President Operations

FIRM NAME	STREET ADDRESS
Alphatec Spine, Inc.	5818 El Camino Real
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlsbad, CA 92008	Medical Device Manufacturer

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.

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An individual medical device manufacturer report submitted per FDA Form 3500A did not indicate in Block H the type of reportable event.

Specifically, five (5) of the nine (9) MDR reports reviewed during the current inspection, which were reported via Form FDA 3500A (MedWatch for mandatory reporting) revealed that Block H was reported as an MDR malfunction event. However, review of the associated complaint records further revealed that the five reports, duirng the complaint evaluation, were actually marked as "Yes" in that a serious injury has occurred. The subject MDR/complaint reports are listed as follows:

MDR-2027467-2009-0005/09-005/8251
MDR-2027467-2009-0006/09-006/9167
MDR-2027467-2009-0009/09-007/9168
MDR-2027467-2009-0009/09-009/9183
MDR-2027467-2009-00013/09013/9372

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, MDR Report No.: 2027467-2009-0005/09-005 was received by the firm on 12/8/08. However, the event was not reported to the FDA until 5/19/09, which is over 4 months late to meet the reporting requirements of filing the MDR report within 30 calendar days.

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OBSERVATION 3

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, MDR Report No.: 2027467-2009-0009/09-007 was received by the firm on 6/17/09. However, the event was not reported to the FDA until 7/20/09, which is thirty-two (32) calendar days later.

OBSERVATION 4

Design outputs that are essential for the proper functioning of the device were not completely identified.

Specifically, the design output (i.e., Drawing No.: 630XX-02 - Solanas Posterior Thoracic Screw Body, Revision B) was released on 12/15/05. However, in May 2009, at the time the firm brought PN: 630XX-02 back in-house from an outside vendor, six lots were manufactured incorrectly (i.e., The screw body only allowed for a 22.5 degree of angulation, yet the design of PN: 630XX-02 required 38 degrees of angulation). Review of CAPA report No.: 09-025, which was generated in response to the incorrect degree of angulation revealed that Drawing No.: 630XX-02, Revisions B and C, did not contain the critical dimensions/specifications/features of the "flats" to ensure correct machining of the screw body/PN: 630XX-02). In addition, the design output/inspection/set-up verification record associated with PN: 630XX-02 (i.e., Quality Processing Inspection Report (Revision A-C) did not provide a call out so that the "flats" are verified for location during the production operations. The design review for PN: 630XX-02, Revision B was approved on 11/8/05, without a justification for the missing critical dimensions/specifications. Finally, the firm has since updated the subject drawing and QIR, however, the firm has not extended the review of other implant families to ensure no other drawings/design outputs are missing their critical dimensions/specifications.

OBSERVATION 5

A process whose results cannot be fully verified by subsequent inspection and test has not been fully validated and approved according to established procedures.

Specifically, in response to the previous FDA-483 item in which the firm had not validated its steam sterilization cycle parameters for resterilization of its spinal implant products, the firm generated Test Report No.: 493 - Report on Evaluation of Effects of Repeat Sterilization, dated 8/11/09. Review of TR-493 revealed that the firm used the Zodiac family of implants/Set No.: PLX34 to run the resterilization challenge studies. The steam sterilization cycle time for the Zodiac family of implants is four (4) minutes. However, the firm has additional implant families in which the steam sterilization is longer than four (4) minutes. For example, the Solanas family of implants is steam cycled for twenty (20) minutes, the Deltaloc

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family of implants are steam cycled for twelve (12) minutes, the Illico and Trestle family of implants are steam cycled for eight (8) minutes. The additional steam sterilization cycles of 8,12 and 20 minutes were not included within the firm's resterilization validation challenge.

OBSERVATION 6

Products that do not conform to specifications are not adequately controlled.

Specifically, Four (4) of twenty-two (22) Solanas family spinal implant complaints reviewed were associated with PN: 63903-HL (hexalobe set screw inserter) stripping. Further review of the associated complaint investigations records revealed the subject part number had been under two (2) nonconformance reports (i.e., 09-0700346 and 09-070455), but the instrument was still utilized with a disposition of Use As Is (UAI) by the firm's Material Review Board (MRB). The instruments were distributed, and subsequently, the four (4) complaint reports were received by the firm.

OBSERVATION 7

Complaint handling procedures have not been defined to ensure that all complaints are processed in a uniform and timely manner.

Specifically, Procedure No.: REG-002 - Complaint Handling Procedure, Revision 002, dated 1/25/10 is not defined in that it does not provide instructions to ensure that non-MDR complaint reports in which the implant/instrument is returned to the firm is closed within a uniform and timely manner. In addition, the following complaint reports have been open and not closed within a timely manner with no documented justification for their on-going open status: Complaint No.: 9206 received on 7/28/09, Complaint No.: 9254 received on 9/4/09 and Complaint No.: 9287 received on 10/2/09.

OBSERVATION 8

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.

Specifically, CAPA Report No.: 08-018 was generated in response to a Return Materials Authorization (RMA) report inspection, which indicated torque handle values below the specification of 25 plus or minus 2.5 in.lbs.. The firm corrected the associated engineering drawing and Quality Processing Inspection Record (QIR) to now include the correct torque value specification and inspection step to check for the correct torque value. However, the firm's preventive action did not include any heightened control(s) over the initial verification of the torque values, which are provided by an outside vendor/supplier.

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OBSERVATION 9

The procedures for implementing corrective and preventive actions were not implemented.

Specifically, Procedure No.: SOP-POL-016 - Corrective & Preventive Action System, Revision E, dated 6/1/09, indicates within Section 7.6 and 7.7, the definitions of when to generate a Low Level Corrective Action (LLCAPA) and a High Level Corrective Action (HLCAPA). However, no LLCAPA or HLCAPA was generated in association with Design History File (DHF) No.: 08-015 for the firm's Solanas implants regarding the complaint attributes of set screws stripping and instrument tip stripping.

OBSERVATION 10

Process validation activities and results have not been fully documented.

Specifically,

a) Test Report No.: 364-04 - Performance Qualification Report Tsugami Screw Machine No.: S-8 (Lot/Work Order Numbers 623958, 624038, and ~~62F4039~~ 624039), Revision B, dated 5/5/09, indicates the specification for the 0F dimension as .200 plus or minus .004. However, review of the Lot 1 Data Collection Form for the subject lot/work order numbers revealed the 0F dimension as 200 plus or minus .005.

b) Test Protocol No.: 364-04 - Performance Qualification Protocol for the Tsugami Screw Machine No.: S-9 (Lot/Work Order No.: 623961), Revision A, dated 5/4/09, indicates that Lot 3 Data Collection Gage No.: 4 (Tool ID No.: GB-286A) had a calibration due date of 4/27/09, which precedes the actual test date of 5/4/09.

OBSERVATION 11

Process control procedures that describe any process controls necessary to ensure conformance to specifications were not defined and implemented.

Specifically,

a) Procedure No.: SET-003 - Cleaning & Disinfection of Returned Materials, Revision A, dated 10/28/09 and Procedure No.: SOP-018 -Returned Materials Authorization Procedure - does not provide instructions that returned implants/instruments associated with complaint allegations are moved to the front of the queue (i.e., prior to the replenishment implants/instruments) for the cleaning and disinfection operations.

b) Procedure No.: SET-003, does not provide instructions for dilutions necessary to formulate a 5% bleach solution, which is used within the firm's implant cleaning and disinfecting area.

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c) The Steris brand washer (i.e., Washer No.: 2/SN: 3608209003) weekly preventative maintenance checks were not conducted for the week of 10/9/09.

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Observation Annotations

Observation 1:	Reported corrected, not verified.	Observation 2:	Reported corrected, not verified.
Observation 3:	Reported corrected, not verified.	Observation 4:	Promised to correct within 180 days.
Observation 5:	Promised to correct within 60 days.	Observation 6:	Promised to correct within 30 days.
Observation 7:	Reported corrected, not verified.	Observation 8:	Corrected and verified.
Observation 9:	Reported corrected, not verified.	Observation 10:	Corrected and verified.
Observation 11:	Corrected and verified.		

*** DATES OF INSPECTION:**
01/20/2010(Wed), 01/25/2010(Mon), 01/26/2010(Tue), 01/27/2010(Wed), 01/28/2010(Thu), 01/29/2010(Fri), 02/05/2010(Fri), 02/08/2010(Mon), 02/11/2010(Thu)

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