

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

19701 Fairchild
Irvine, CA 92612
(949) 608-2900 Fax: (949) 608-4417
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

02/04/2015 - 03/13/2015*

FEI NUMBER

2027467

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael J. Plunkett, Chief Operating Officer (COO)

FIRM NAME

Alphatec Spine, Inc.

STREET ADDRESS

5818 El Camino Real

CITY, STATE, ZIP CODE, COUNTRY

Carlsbad, CA 92008

TYPE ESTABLISHMENT INSPECTED

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:

FDA-483 Item 1 is a repeat observation

OBSERVATION 1

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, Between 1/2009 and 4/25/2014, the firm has on file 32 complaint reports for the Illico Screw Extender (Part No.'s 73724, 73772 and 73779) for dimples/tabs partially or fully breaking off during the implant surgical procedure, which were not reported to the FDA as MDR malfunction reports. The firm's rationale for not reporting these events as MDR reportable was because there was no associated harm to the patient or delay in the procedure. However, this decision pathway is flawed in that the definition of a malfunction event does not necessitate that patient harm (i.e., serious injury or death) or procedural delay to include surgical intervention must have occurred, rather it necessitates the probability of patient harm occurring or the need to conduct surgical intervention to prevent harm, if the event were to recur. In addition, the firm has on file five (5) additional complaints for screw extender broken tabs, which were reported as MDR serious injury reports due to a delay in the surgical procedure in an attempt to remove the broken off tabs. See Table 1 below for a listing of the 32 complaint reports, not reported as MDR malfunction reports:

Table 1 - Listing of Illico Screw Extender Complaints for broken dimples/tabs (1/2009 through 4/25/2014)

Complaint No.:	Investigation Results	Report Date	Part No.:
CPL-001406	Tab broken off	2/20/12	73724
CPL-001900	Tab broken off	8/14/12	73724
CPL-001991	Both tabs broken off	9/27/12	73724

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CPL-002111	Both tabs broken off	11/18/12	73724
CPL-002137	Both tabs broken off	11/27/12	73724
CPL-002214	Both tabs broken off	1/2/13	73724
CPL-002316	Tab broken off	1/31/13	73724
CPL-002592	Tab broken off	5/15/13	73724
CPL-002705	Both tabs broken off	6/20/13	73772
CPL-002734	Both tabs broken off	7/8/13	73772
CPL-002804	Tab broken off	7/22/13	73724
CPL-002813	Tab broken off	7/26/13	73724
CPL-002918	Both tabs broken off	9/12/13	73772
CPL-002928	Tab broken off	9/17/13	73724
CPL-002929	Both tabs broken off	9/17/13	73772
CPL-002960	Tab broken off	9/26/13	73724
CPL-002991	Both tabs broken off	10/9/13	73772
CPL-003055	Tab broken off	11/20/13	73724
CPL-003106	Tab broken off	12/18/13	73772
CPL-003113	Tab broken off	12/19/13	73772
CPL-003134	Both tabs broken off	1/8/14	73724
CPL-003201	Tab broken off	2/13/14	73724
CPL-003234	Balls of flaps breaking off	3/3/14	73772
CPL-003293	Tab broken off	4/2/14	73724
CPL-003294	Tab broken off	4/2/14	73724
CPL-003295	Tab broken off	4/2/14	73724
CPL-003298	Tab broken off	4/2/14	73779
CPL-003310	Tab broken off	4/7/14	73779
CPL-003312	Tab broken off	4/7/14	73772
CPL-003313	Tab broken off	4/7/14	73779
CPL-003368	Tab broken off	4/23/14	73779
CPL-003369	Tab broken off	4/23/14	73724

OBSERVATION 2

The design was not validated under actual or simulated use conditions.

Specifically, originally/per Change Order (CO) No.: 09-196, release date 5/18/2009 through 8/5/2009, the firm implemented the launch of the Illico MIS Screw Extension (SE) System as part of the Design History File (DHF) No.: 07-021 via Validation Report No.: TR-419 - Design Validation and Simulated Use Lab for the Illico SE Posterior Fixation System, Revision A., On 11/17/2011, per CO No.: (b) (4), the firm released Part No.: (b) (4) (b) (4) for use with Part No.: (b) (4) (Illico Reduction Screw Extender). However, the (b) (4) design was not validated in that CO No.: (b) (4) indicates, "Verification and validation is not required. All of the same mechanisms that have already

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been validated are being used." This statement refers to Validation Report No.: TR-419. Yet, this statement is invalid in that the (b) (4) design/PN: (b) (4) was not part of the design associated with Validation Report No.: TR-419. In addition, post the release of CO No.: (b) (4), the firm's number of complaints for "broken tabs," has increased (i.e., prior to the release of CO No.: (b) (4) the firm had five (5) complaints on file from 1/2009 through 1/2013; post the release of CO No. (b) (4) (the first set built date was (b) (4)) the firm has approximately 28 complaint reports on file ranging from 5/2013 through 4/25/2014, which were MDR reportable events.

OBSERVATION 3

The design history file was not established.

Specifically, the firm's (b) (4) (spinal implant device) was acquired from another medical device company in (b) (4). However, the firm has no design history file (DHF) for the (b) (4) device prior to (b) (4) (i.e., Drawing No.: (b) (4), Revision D) and there is only one (1) DHF record post (b) (4) (i.e., Drawing No.: (b) (4) - (b) (4), Revision R, release date 8/3/2009). The (b) (4) family of medical devices was cleared for marketing via multiple 510 (k) submissions to include 2005 and 2007, and there was a product recall for the (b) (4). In addition, in the event the firm needs to conduct a failure investigation, implement a product recall or submit a MDR report for the (b) (4) device, there would be a gap in the investigation/analysis in that the DHF to include device specifications (i.e., design outputs) would be unavailable for review.

OBSERVATION 4

A device history record has not been adequately maintained.

Specifically, the firm acquired the (b) (4) (spinal implant device) from another medical device company in (b) (4). However, the only device history records (DHRs) on file for Part No.: (b) (4) - (b) (4), Final Assembly, (b) (4), Revision B/Catalog No.: (b) (4) are dated (b) (4) and (b) (4) and for Revision C of Part No.: (b) (4)/Catalog No.: (b) (4) they are dated (b) (4) through (b) (4). The (b) (4) family of medical devices was cleared for marketing via multiple 510 (k) submissions to include 2005, 2007, 2008 and 2009. On (b) (4), the FDA was notified of manufactured and distributed (b) (4) devices under a product recall. In addition, post the acquisition, the firm is responsible for conducting a failure investigation, implementing a product recall or submitting a MDR report, if necessary for the (b) (4) device. However, the lack of DHR's would result in an inadequate failure investigation in that there would be a gap where the DHR data would be unavailable for review.

OBSERVATION 5

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, the firm acquired the (b) (4) (spinal implant device) from another medical device company in (b) (4). Previously, on (b) (4), the (b) (4) device was recalled, however, the firm has no records of the recall/corrections and removals on file to include receipt and final disposition of the returned units under recall nor any records associated with what preventive actions were put into place to prevent recurrence of the problem.

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OBSERVATION 6

Quality system procedures and instructions have not been established.

Specifically, the firm acquired the (b) (4) (i.e., spinal implant (b) (4)) medical device family from another medical device company in (b) (4) . However, the firm has no procedures in place to ensure the quality system records associated with the acquired device to include device history records, drawings, specifications, procedures, etc., were received at the time of the acquisition.

OBSERVATION 7

Procedures for corrective and preventive action have not been adequately established.

Specifically,

a) Procedure No.: SOP-025 - Corrective and Preventive Action (CAPA) System, Revision L is not defined in that the procedure does not provide instructions or a linkage to an action or alert level for the (b) (4) complaint trending data, which is reviewed at the (b) (4) trend review meetings. For example, the (b) (4) complaint rate by product line is determined by the "(b) (4)

" The determined unit of display is in percentage. However, the firm has not established an alert or action level to meet the established threshold specified within Section 6.1.1.1 of Procedure No.: SOP-025, "(b) (4)

b) Procedure No.: SOP-025 is not defined in that the Frequency Table (frequency of the event occurrence) listed within Section 6.2.1.1 does not provide a definition for the quantitative estimation formula associated with (b) (4)), (b) (4)); (b) (4)); and (b) (4)).

OBSERVATION 8

Procedures for design validation have not been adequately established.

Specifically, Procedure No.: PRO-000003 - Risk Management, Revision F is not defined in that Table 2 - (b) (4) (b) (4)

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OBSERVATION 9

Procedures for acceptance activities have not been adequately established.

Specifically, Document/Procedure No.: QCP-042 - Supplied Material Inspection, Revision J is not adequately defined in that Section No.: 6.9.8.1 provides instructions, "(b) (4)". However, the instructions do not define where on the ^{(b) (4)} (i.e., beginning, middle, end, etc.) to take the measurements. For example, regarding the receipt of Part No.: (b) (4) / Lot No.: (b) (4) on (b) (4), which is the (b) (4) stock for use in the machining/manufacturing of the firm's spinal implant devices, the instructions do not define where on the ^{(b) (4)} (i.e., beginning, middle, end, etc.) to take the measurements.

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	Scott K. Zika, Investigator / <i>[Signature]</i>	03/13/2015

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Observation Annotations

Observation 1:	Promised to correct within 90 days.	Observation 2:	Promised to correct within 90 days
Observation 3:	Under consideration.	Observation 4:	Under consideration.
Observation 5:	Under consideration.	Observation 6:	Under consideration.
Observation 7:	Promised to correct within 60 days.	Observation 8:	Promised to correct within 60 days.
Observation 9:	Promised to correct within 45 days.		

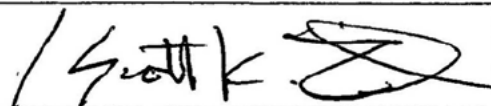
*** DATES OF INSPECTION:**

02/04/2015(Wed), 02/05/2015(Thu), 02/06/2015(Fri), 02/09/2015(Mon), 02/10/2015(Tue), 02/11/2015(Wed), 02/13/2015(Fri), 02/18/2015(Wed), 02/20/2015(Fri), 02/23/2015(Mon), 02/24/2015(Tue), 03/10/2015(Tue), 03/13/2015(Fri)

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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 judgement, 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."