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	07/25/2012 - 09/11/2012* FEI NUMBER 3004884943

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Roger K. Williams, President

FIRM NAME	STREET ADDRESS
Spinal Solutions, LLC	26157 Jefferson Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murrieta, CA 92562-9561	Medical Device Specification Developer

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 WE OBSERVED:

OBSERVATION 1

Procedures for design control have not been established.

Specifically, you design and develop the Lancer Pedicle Screw System (Lancer), which has various indications for use including treatement of severe spondylolisthesis of L5-S1 vertebrae and immobilization and stabilization of spinal segments as an adjunct to fusion. As such, you have not defined, documented, and implemented: 1) a design and development plan; 2) a design history file; 3) design inputs; 4) design output; 5) design review; 6) design verification; 7) design validation, including risk analysis; and 8) design transfer. Further, there have been no procedures established for the above activities or for design change.

OBSERVATION 2

Procedures for device history records have not been established.

Specifically, your firm consigns kits of spinal fixation systems and interbody fusion devices to Surgical Sales Representatives/independent contractors. Upon implantation of devices, accessories, and/or components contained in these kits, replacements are shipped to the independent contractor from your facility or directly from your supplier to re-fill the kit. You have not established a procedure to document the storage and filling process of kits with components that have been consigned to Surgical Sales Representatives/independent contractors. Further, there are no records available documenting the: 1) date components are put into kits, 2) quantity contained in each kit, 3) quantity distributed, 4) acceptance activities

AMENDMENT 1

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Dogan H. Harris, Investigator Minh L. Phan, Investigator Sonya L. Karsik, Investigator Marcus F. Yambot, Investigator	09/11/2012

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performed, 5) primary labels and labeling used, and 6) any identification numbers used for these kits and components.

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, your firm currently kits, sells, and distributes finished medical devices, including spinal fixation system kits, components, interbody fusion devices, and instruments, supplied to you by Companies (b) (4) These devices are also sold for you by independent contractors. Your existing agreements with Companies (b) (4) and (b) (4) and with independent contractors do not describe the responsibility of each party for quality requirements, inlcuding complaints, Medical Device Reports, Device History Records, Design History Files, labels/labeling, product design and changes, where appropriate. There is no agreement in place with Companies (b) (4)

OBSERVATION 4

Procedures to control labeling activities have not been established.

Specifically, your firm has not defined, documented, and implemented a procedure to address the provisions of labeling, such as Instructions For Use, with finished spinal fixation system and interbody fusion device kits. For instance, on 8/3/2012 Company (b) (4) kit was repacked and the DHR for this kit, (b) (4) did not document or reference the labeling used for this kit.

AMENDMENT 1

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.

*** DATES OF INSPECTION:**
07/25/2012(Wed), 07/31/2012(Tue), 08/03/2012(Fri), 08/09/2012(Thu), 08/15/2012(Wed), 08/22/2012(Wed), 09/11/2012(Tue)

AMENDMENT 1

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