DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild 07/25/2012 - 09/11/2012* Irvine, CA 92612 (949) 608-2900 Fax: (949) 608-4417 3004884943 Industry Information: www.fda.gov/oc/industry NAME AND THE OF DISMIBUAL TO WHOM REPORT ISSUED Roger K. Williams, President 26157 Jefferson Ave Spinal Solutions, LLC 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 fam 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

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INSPECTIONAL OBSERVATIONS

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Spinal Solutions, STATE, ZIP CODE, COUNTR	ons, LLC	26157 Jeffer	son Ave	
Murrieta, CA	92562-9561	Medical Devi	ce Specification De	eveloper
performed, 5) prima	ry labels and labeling used, and 6) any id	lentification number	s used for these kits and con	nponents.
OBSERVATION 3		N.	ende en ender en ender en	
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	rm currently kits, sells, and distributes fir			
components, interbo	ody fusion devices, and instruments, supp	lied to you by Com	panies (b) (4) These devices a	re also sold for
you by independent	contractors. Your existing agreements woonsibility of each party for quality requi	ith Companies (b) (e)	and and with independent	Contractors do
History Records, De	esign History Files, labels/labeling, produ	ict design and chang	es, where appropriate. Ther	e is no agreement
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