DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry	06/14/2010 - 07/02/2010* FEI NUMBER 3002498892

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Randall R.Theken, President

FIRM NAME	STREET ADDRESS
Theken Spine LLC	1800 Triplett Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Akron, OH 44306-3311	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 WE OBSERVED:

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, during this inspection 11/35 complaint files reviewed (31%) showed MDR reportable events which were not submitted to FDA.

1. Complaint # 09-0710-01, dated 07/10/2009, involved two Atoll locking screws separating from the saddle during surgery.
2. Complaint # 09-0623-01, dated 06/23/2009, involved an Atoll locking screw separating from the saddle.
3. Complaint # 09-0828-01, dated 09/28/2009, involved a Vu aPOD breaking during insertion.
4. Complaint # 09/0624-01, dated 06/24/2009, involved set/locking screws separating from the saddle.
5. Complaint # 09-0805-01, dated 08/05/2009, involved a Coral locking screw stripping during surgery.
6. Complaint # 2010-02-00239-C, dated 02/12/2010, involved two Coral screws breaking during surgery.
7. Complaint # 09-0826-01, dated 08/26/2009, involved a Rod Reduction Tower bending and delaying surgery.
8. Complaint # 2010-04-00532-C, dated 04/28/2010, involved discovering, during surgery, that an Atoll cross connector inserter tip would not fit into the locking screws and the cross connector could not be implanted.
9. Complaint # 09-0616-01, dated 06/16/2009, involved a Vu aPOD spin plate breaking during surgery. The spin plate was not removed but was rotated into the neutral position and left in place.
10. Complaint # 09-0617-02, dated 06/17/2009, involved a Polyaxial Screw head popping off after insertion.
11. Complaint # 09-0917-01, dated 09/17/2009, involved an Adjustable Cross Connector breaking during surgery.

Also, 5/34 (15%) MDR reports reviewed since January, 2009 were not reported within 30 days.

1. Complaint # 2010-05-00043-C, dated 05/05/2010, with awareness date 05/03/2010, was not submitted until

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06/08/2010. Atoll cross links could not be used in surgery because when tightening the cross link set screws, the side-tabs bent and no longer allowed a tight fit to the screw heads.

2. Complaint # 2010-02-00191-C, dated 02/10/2010, with awareness date 02/09/2010, was not submitted until 04/20/2010. Coral instruments broke during surgery.
3. Complaint # 2010-04-00152-C, dated 04/09/2010, with awareness date 04/07/2010, was not submitted until 05/20/2010. A Kerrison-Rongeur punch broke during surgery.
4. Complaint # 2010-04-00267-C, dated 04/16/2010, with awareness date 04/14/2010, was not submitted until 06/09/2010. A 14mm disc shaver broke during surgery.
5. Complaint # 2010-04-00497-C, dated 04/27/2010, with awareness date 04/27/2010, was not submitted until 06/15/2010. A Coral screw head broke off during surgery.

Additionally, there were another 14 complaint files associated with corrective actions that showed MDR reportable events which were not reported to FDA.

1. Complaint # 08-0218-01, dated 02/18/2008, involved an Atoll locking screw that separated from the saddle.
2. Complaint # 09-0706-04, dated 07/06/2009, involved Atoll locking screws that separated from the saddle.
3. Complaint # 09-1014-01, dated 10/14/2009, involved an Atoll locking screw that separated from the saddle.
4. Complaint # 08-0303-02, dated 03/03/2008, involved bent tips on Vu E-Pod Inserters.
5. Complaint # 08-0304-03, dated 03/04/2008, involved broken tips on Vu E-Pod Inserters.
6. Complaint # 08-0822-02, dated 08/22/2008, involved tips broken on Vu E-Pod Inserters.
7. Complaint # 08-1024-01, dated 10/24/2008, involved tips broken on Vu E-Pod Inserters.
8. Complaint # 09-0128-01, dated 01/28/2009, involved broken tips on Vu E-Pod Inserter.
9. Complaint # 09-0224-01, dated 02/24/2009, involved broken tips on Vu E-Pod Inserter.
10. Complaint # 09-0226-02, dated 02/26/2009, involved broken tips on Vu E-Pod Inserter.
11. Complaint # 08-1204-04, dated 12/04/2008, involved broken tip on Manta Ray Inserter.
12. Complaint # 08-1210-01, dated 12/10/2008, involved broken tip on Manta Ray Inserter.
13. Complaint # 08-1210-04, dated 12/10/2008, involved broken tip on Manta Ray Inserter.
14. Complaint # 08-1003-02, dated 10/03/2008, involved bent spin plate lockers on Vu aPOD.

OBSERVATION 2

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

Specifically,

1) The firm utilizes a (b) (4) washer in order to clean spinal implant kits (containing various sizes of spinal implant devices/tools/spacers) which have been returned to the firm. Typically, these kits have been introduced into a sterile field and used during a surgery. The kits and kit components are supplied clean but non-sterile. Sterilization is done by the end user.

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The tools and spacers used are potentially contaminated during surgery and are considered re-usable. The spinal implant devices are single-use devices, although there is a chance that these devices have been contaminated by the process of a surgeon attempting to select the proper size of an implant and returning devices back into the kit.

The firm has not fully validated this cleaning process for time, temperature or amount/concentration of detergent. The firm has performed some operational qualifications (OQ) for the instrument, but has not performed process qualifications (PQ). Additionally, the firm is not monitoring these variables during processing.

2) The firm has validated steam sterilization as the method for sterilizing all implants/tools and trays distributed by the firm. In all cases a fully loaded tray is to be sterilized at 270°F for a minimum of ten minutes. These products do not have an expiration date or a maximum number of sterilization cycles. Worst case scenario for sterilization cycles is estimated at 112 surgeries per year for 10 years yielding 11200 minutes or 187 hours of sterilization time. The firm has not shown that the following materials (b) (4) or (b) (4)) used in numerous device are not adversely affected by the repeat sterilization cycles.

(b) (4) is a component of tool handles in the majority of kits. (b) (4) degradation was only tested for (b) (4) cycles at (b) (4) (b) (4) each for a total of (b) (4) hours.

(b) (4) (b) (4) glue is used on tool handles in the (b) (4) and (b) (4) kits. The glue was only tested for (b) (4) cycles at (b) (4) minutes yielding (b) (4) hours of sterilization time.

OBSERVATION 3

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

Specifically,

1) The following corrective action files show device malfunctions identified through complaints/trending which resulted in MDR reportable events and design changes. These CAPA files did not show adequate justification why no field action was required.

CAPA F2009-030 was the result of 5 complaints involving Atoll locking screw assemblies (spinal implants). Three of the complaints involved lot number W9913 of the device and the other 2 complaints did not have the lot number identified. According to the firm's Risk Analyses for the product (done as a FMEA), this failure is associated with a "High" severity as described in the firms technical file 4.5.3 which addresses risk analyses.

The root cause of the problem was identified to be inadequate swaging where the "mushroom" head is not completely formed.

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In response to this issue, the contract manufacturer added a new swaging tool and added a 100% visual inspection to all parts to ensure a proper swage.

CAPA F2009-024 was the result of 6 complaints involving Vu ePOD inserter tips (spinal implant tool) twisting or breaking. According to the firm's Risk Analyses for the product (done as a FMEA), this failure is associated with a "High" severity as described in the firms technical file 4.5.3 which addresses risk analyses.

The root cause of the problem was identified as the tip thickness of the tool. The firm made a design change through ECO 721 which added thickness to the tip to increase strength.

CAPA F2009-046 was the result of a complaint involving Manta Ray spinal implant devices. The failure involved revision surgery after 2 screws had backed out of an anterior cervical plate. These screws are usually held in place by lock down plate. The firm performed a Health Hazard Evaluation (HHE) of the malfunction. The HHE concluded that the malfunction was High Risk with "Field Action Required". The firm attempted to justify not performing a field action as "Technique, training, and running design changes have been put in place". The HHE procedure does not appear to give this option for hazards associated with a High Risk, only for Moderate Risk devices.

2) 12/12 non conforming material reports reviewed stated that a corrective action was needed and refers to CAPA procedure 4.14. None of these corrective actions were formally managed through the CAPA system but rather through e-mails and not according to any procedures.

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

Observation 3: Promised to correct.

*** DATES OF INSPECTION:**
06/14/2010(Mon), 06/15/2010(Tue), 06/16/2010(Wed), 06/17/2010(Thu), 06/18/2010(Fri), 06/23/2010(Wed), 06/24/2010(Thu), 06/25/2010(Fri), 06/28/2010(Mon), 07/02/2010(Fri)

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