DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	12/08/2008 - 12/10/2008
	FEI NUMBER 3005101424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James Andrew Pierce, Vice President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Craniomaxillofacial Division	750 Trade Centre Way Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Portage, MI 49002-0482	Medical Device Distributor

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

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

Specifically, during a review of (b) (4) complaint files (Product Experience Reports or PERs), several were observed that did not have complete investigation documentation, and/or deviated from the Stryker Osteosynthesis investigation procedure OMV(b) (4) The procedure requires either (b) (4) (b) (4) Status reports were not available in any of these cases as of Dec. 9, 2008. The following PERs are examples:

a) (b) (4) received (aware of) Aug. 7, 2008 and entered into PER system Aug. 13, 2008 for 10 g BoneSource Classic, catalog no. 7941910, lot no. unknown. The complaint involved an infection and an MDR was submitted. This PER was released to Stryker Osteosynthesis for investigation on Aug. 13, 2008.

b) (b) (4) received (aware of) Sept. 15, 2008 and entered into PER system Oct. 13, 2008 for Extra Large Custom Cranial Implant, catalog no. 5400104, lot no. 0520812918. The complaint involved an infection and revision surgery, and an MDR was submitted. This PER was released to Stryker Osteosynthesis for investigation on Oct. 13, 2008.

c) (b) (4) received and entered into PER system Oct. 7, 2008 for Cannulated Screwdriver Blade, catalog no. 07-40220, lot no. unknown. The complaint involved a blade break. This PER was released to Stryker Osteosynthesis for investigation on Oct. 7, 2008.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	William D. Tingley, Investigator Eric S. Pittman, Investigator Gary D. Urbiel Goldner, Investigator	12/10/2008

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Observation Annotations

Observation 1: Promised to correct.

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SEE REVERSE OF THIS PAGE	William D. Tingley, Investigator WDT Eric S. Pittman, Investigator ESP Gary D. Urbiel Goldner, Investigator GDUG	12/10/2008