DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION				
300 River Place, Suite 5900]	12/08/2008 - 12/10/2008				
Detroit, MI 48207	F	EINUMBER				
(313) 393-8100 Fax:(313) 393-8139	, ,	3005101424				
Industry Information: www.fda.gov/oc/indu	stry					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
TO: James Andrew Pierce, Vice President	and General M	anager				
Stryker Craniomaxillofacial Division	750 Trade Centre Way Ste 200					
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 complaint files (Product Experience Reports or PERs), several were observed that did not complete investigation documentation, and/or deviated from the Stryker Osteosynthesis investigation procedure The procedure requires either (b) (4)

Status reports were not

available in any of these cases as of Dec. 9, 2008. The following PERs are examples:

- (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) (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.
- (b) (4) eceived 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.

	EMPLOYEE(S) SIGNATURE William D. Tingley, Investigator	DATE ISSUED
SEE REVERSE	Eric S. Pittman, Investigator Gary D. Urbiel Goldner, Investigator	12/10/2008
	INCRECTIONAL OPCEDVATIONS	DAGE 1 OF 2 DAGE

Date of the state	DEPARTMENT OF E	IEALTH AND HU! DRUG ADMINISTRA	TION		goggg an See Co. Co. See Co. Co. See	
Detroit, MI 48207 (313) 393-8100 Pax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry TO: James Andrew Pierce, Vice President and General Manager FIRST NAME Stryker Craniomaxillofacial Division TYPE ESTABLISHEN MARKETED FORTAGE, MI 49002-0482 FERNAMEN Medical Device Distributor	ISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSE		000	
Industry Information: www.fda.gov/oc/industry MANGE ADDITION OF THE PROPERTY	Petroit, MI 48207		FEI NUMBER	008 - 12/10/2	008	
TO: James Andrew Pierce, Vice President and General Manager First Name STREET ADDRESS			3005101	3005101424		
STEET ADDRESS STLYYKEY Craniomaxillofacial Division 750 Trade Centre Way Ste 200 TYPE ESTABLISHENT INSPECTED Medical Device Distributor Medical Device Distributor	AME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	naustry				
Stryker Craniomaxillofacial Division 750 Trade Centre Way Ste 200 OFF. STATE, 200 CODE COUNTRY PORTAGE, MT 49002-0482 Medical Device Distributor	10: James Andrew Pierce, Vice Preside	nt and Gene	ral Manager			
Portage, MI 49002-0482 Medical Device Distributor						
	ortage, MI 49002-0482	Medical	Device Dist	ributor		

-	EMPLOYEE(S) SIGNATURE William D. Tingley, Investigator Eric S. Pittman, Investigator Gary D. Urbiel Goldner, Investigator	12/10/2008
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DATE(S) OF INSPECTION DISTRICT ADDRESS AND PHONE NUMBER 12/08/2008 - 12/10/2008 300 River Place, Suite 5900 FEI NUMBER Detroit, MI 48207 3005101424 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry TO: James Andrew Pierce, Vice President and General Manager FIRM NAME STREET ADDRESS 750 Trade Centre Way Ste 200 Stryker Craniomaxillofacial Division TYPE ESTABLISHMENT INSPECTED CITY, STATE, ZIP CODE, COUNTRY Portage, MI 49002-0482 Medical Device Distributor

Observation Annotations

Observation 1:

Promised to correct.

EMPLOYEE(S) SIGNATURE

William D. Tingley, Investigator

Eric S. Pittman, Investigator

Gary D. Urbiel Goldner, Investigator Coug

DATE ISSUED

12/10/2008

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SEE REVERSE

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