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	05/11/2009 - 05/15/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Bradford L. Saar, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Medical Div. of Stryker Corporation	3800 E. Centre
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Portage, MI 49002	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

Rework and reevaluation activities have not been fully documented in the device history record.

Specifically,

There is no documentation of the failure during in process testing which resulted in the product being reworked. S3 custom bed Order Number (b) (4) serial number (b) (4) dated 3/20/2009 resulted in a rework of the bed for "load cell doesn't work". There is no documentation to show the results of the initial calibration test for the load cell that led to this failure. A rework was performed adn the passing calibration results were documented on the Product history card as passing results.

In addition, there was no investigation into the scope of the problem for missing bolts and washers on the Electric Stretcher catalog part number 1550000000 as seen in complaint PER (b) (4) dated 12/30/2008. This investigation did not include evaluation of units manufactured prior to the procedural instruction change on 2/17/09.

OBSERVATION 2

Procedures were not implemented for monitoring and control of process parameters for validated processes.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/15/2009

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Corporate SOP (b) (4) Validation states that (b) (4) . Revalidation procedure for the Caster Mount W/O (b) (4) dated 02/05/2009 shows that a validation sample size of (b) (4) was pulled. Re work procedure discription states to drill (b) (4) . Re work inspection states to inspect first, middle, and end. Of the (b) (4) validation samples pulled, only (b) (4)) units were tested for pass or failure and accepted as a validation acceptance criteria.

OBSERVATION 3

Procedures for changes to methods were not implemented.

Specifically,

CAPA (b) (4) addresses the vendor changing the stamping and bending direction of the Brake Plate (3006-200-356) in August 2008. There is no documentation of review and disposition of inventory of brake plates in house prior and up to the vendor change. No inspection was documented to assure the brake plate is stamped such that the sharp edge is toward the tooth as dictated in the CAPA and in accordance to the change in stamping at the vendor.

OBSERVATION 4

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,

No MDR was filed for complaint PER# (b) (4) dated 3/30/09 in which an eye surgery stretcher model 1079 dropped while a patient was being prepped for eye surgery. The complaint alleged an abrupt falling of the head of the eye surgery stretcher and the sterile area was breeched. The firm failed to provide evidence that the failure of the device could not result in potential harm to the customer.

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OBSERVATION 5

Employees have not been adequately trained.

Specifically,

Sales representatives, complaint handlers, and service technicians do not always obtain complainant information during the initial contact with the complainant. PER (b) (4) dated 4/21/09 resulted in the consumer service calling the sales representative several times for follow-up information which could have been obtained during initial contact.

OBSERVATION 6

Complaint handling procedures for receiving complaints have not been implemented.

Specifically,

Corporate SOP (b) (4) dated 09/26/2008 states that patient involvement shall be documented and a rationale shall be provided if the field is unknown. This was not always completed as evidence by Complaint PER (b) (4) dated 04/28/2009 and PER (b) (4) dated 04/15/09.

OBSERVATION 7

Procedures were not defined for the validation or verification of design changes before their implementation.

Specifically, a design change to (b) (4), part number 2035-032-095, was made from rev. (b) (4) to rev. (b) (4) to provide more (b) (4) and (b) (4) on the Epic II critical care beds. The change from rev. (b) (4) to rev. (b) (4) of part number 2035-032-095 involved (b) (4) rev. (b) (4). There have been at least (b) (4) complaints involving Epic II beds with rev. (b) (4) of the fowler bearing support alleging the fowler was jerky, noisy, and/or would not go up and down in a smooth motion. The change from rev. (b) (4) to rev. (b) (4) was released into production without verification testing per ECO-(b) (4).

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Corrected and verified.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct by 6/30/2009.
Observation 7:	Promised to correct.		

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