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	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	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

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

Specifically,

The following processes are not fully validated:

1. The process for manufacturing the Clover Catheters and Silver Ex-Fen Catheters is not fully validated.
    a. The female luer hub component of the Clover Catheter and Silver Ex-Fen Catheters is an injection-molded part. There is evidence of dimensional failures, short shots, flash, loose foreign matter, and embedded contamination during the validation runs with injection molding operating parameters set at the minimum and maximum values. There is no documentation that these runs were repeated at revised minimum and maximum injection molding parameters to establish a range of operating parameters per the validation protocol (b) (4) . The current set-up sheet for the injection molding process used in routine production of the female luer contains the minimum and maximum injection molding parameters that were used during the failing runs. Additionally, the nominal runs performed during validation (b) (4) were not representative of actual production. The nominal runs were approximately (b) (4) long. Routine production is approximately (b) (4) .

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b. The extrusion process of manufacturing the tubing component of the Clover Catheter and Silver Ex-Fen Catheters has not been validated. According to personnel at Stryker Instruments, the outer diameter of the catheter tubing is the only dimension that is continuously monitored (using a (b) (4)). Other qualities of the catheter tubing, such as tensile testing, are tested using one sample at the beginning and one sample at the end of each reel.

2. The (b) (4) bonding process of the glass restrictor to the male luer of the Stryker Auto-Fuser PainPump is not completely validated. The documentation available at Stryker Instruments (translated from (b) (4)) involves a number of limited test runs to determine a range of operating parameters. There is no documentation of runs being performed at the nominal parameters as part of process validation representing routine production to determine the stability of the (b) (4) bonding process when run over time. There is no documentation that any destructive cross-sectional examination of the quality and (b) (4) bond of the glass restrictor to the male luer connector was performed. The (b) (4) bonding process was identified as the root cause of a Stryker Auto-Fuser infusion pump that was found to over-infuse by (b) (4).

OBSERVATION 2

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,

(b) (4) complaints received by the firm between January 23, 2009 and February 18, 2009 reported leakage of oil or a black oil, substance, or material from the surgical instrument into either the sterile field or the patient wound during a surgical procedure. These complaints have not been reported as MDR's. For example:

a. PER # (b) (4) of January 23, 2009 reported:
   i. (b) (4) ."
   ii. "(b) (4) ."

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b. PER #(b) (4) of January 27, 2009 reported:
   i. "(b) (4) [redacted] ."
   ii. "..(b) (4) [redacted] ..."

c. PER (b) (4) of February 5, 2009 reported, "(b) (4) [redacted] ."

d. PER (b) (4) of February 17, 2009 reported, "(b) (4) [redacted] ."

e. PER #(b) (4) of February 18, 2009 reported:
   i. "(b) (4) [redacted] ."
   ii. "..(b) (4) [redacted] ."

OBSERVATION 3

Potential suppliers and contractors were not sufficiently evaluated and selected on the basis of their ability to meet specified requirements.

Specifically,

The completeness and adequacy of process validations for processes which cannot be fully verified by inspection and testing is not fully assessed during supplier evaluations. For example:

1. The supplier evaluation process for the approval of the contract manufacturer of the Stryker Auto-Fuser PainPump indicates that a functional team evaluated the (b) (4) bonding process of the glass restrictor to the male luer connector. The documentation available at Stryker Instruments (translated from (b) (4)) involves a number of short test runs to determine a range of operating parameters. There is no documentation that any destructive cross-examination of the (b) (4) bond of the glass restrictor to the male luer connector was performed during process validation to assess the quality and regularity of the bond. In spite of this lack of documentation, the functional team approved the validation documents from the contract manufacturer. The (b) (4) bonding process was identified as the root cause of a Stryker Auto-Fuser PainPump that over-infused by (b) (4)%.

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OBSERVATION 8

A validated process was not performed by a qualified individual.

Specifically,

There is no documentation of the qualification of employee retraining in the operation of the Automated Optical Inspector (AOI) machine. During original qualification on the AOI machine on 4/6/06 using known defective boards, employees had difficulty observing defect boards that were observed by the AOI machine. The Process Qualification Characterization Test Report stated all defects were identified correctly by the system, but defects were identified with abnormalities by the operators. During operations, the Quality Operators override defects observed by the AOI machine.

In addition, Disc Monitor PCB Set work order number (b) (4) passed (b) (4) visual in process inspection under IPC (b) (4) standard inspectional guidelines was released based on final inspection of 2/11/09. Defects, including backwards pressure sensors, were then discovered at Stryker Puerto Rico on the Disc Monitor PCB Set.

OBSERVATION 9

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 evidenced by:

- Complaint (b) (4) for the RF Multi Gen unit dated 5/01/2009
- PER # (b) (4) of January 6, 2009 for an Automatic High Vacuum Foot Pump (Catalog # 0206500000)
- PER # (b) (4) of March 6, 2009 for a Repair Core U Drill (Catalog # 5400100000R)
- PER # (b) (4) of April 16, 2009 for a Micro Drill Medium Straight Attachment (Catalog # 5100015250)

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