DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax: (913) 752-2111 Industry Information: www.fda.gov/oc/industry	03/09/2009 - 03/12/2009* FEI NUMBER 3002970984

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Maurice P. Keezer, Contract Administrator

FIRM NAME	STREET ADDRESS
Saturn Orthopedics	5100 NE Chouteau Trfwy.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kansas City, MO 64119	medical device specifications developer

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

The procedures for implementing corrective and preventive actions were not established and documented.

Specifically, the firm has no written Corrective and Preventive Action (CAPA) procedure, which includes procedures for:

- Routinely reviewing sources of quality data (such as complaints, returns and repairs) to identify quality problems
- Investigating causes of product non-conformities
- Implementing changes at contract manufacturers and process vendors to prevent or correct quality problems
- Communicating information on quality problems to upper management

OBSERVATION 2

Procedures for acceptance activities were not documented and implemented.

Specifically, there are no written procedures for visual inspection and/or functional testing of new and refurbished (b) (4) handpieces and osteotomes.

OBSERVATION 3

Acceptance activities were not documented.

Specifically, inspection and acceptance/rejection of incoming (b) (4) handpieces and osteotomes (new and refurbished) has not been documented per the firm's procedure on the "Acceptance/Rejection Report of Incoming Products."

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James D. Planchon, Investigator Jessica L. Peterson, Investigator	03/12/2009

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OBSERVATION 4

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically, distributors and sales reps have not documented all surgical uses of rental (b) (4) kits under their control on standardized "useage reports," identifying all (b) (4) kit components used in the procedure. Further, the current "useage report" form does not require sales reps to confirm that cleaning /sterilization of the rental kit was performed prior to return and reissue.

OBSERVATION 5

Service reports were not documented.

Specifically, there is no documentation of the refurbishing of used osteotomes, gouges, and punches, including:

- No documentation of re-sharpening / re-grinding by the contract refurbisher;
- No documentation of polishing (sand-bead blasting).

OBSERVATION 6

Complaint handling procedures for receiving and evaluating complaints have not been established.

Specifically, the firm has not established a Complaint File or devised a Complaint Form for recording user complaints.

OBSERVATION 7

Procedures have not been defined and followed to prevent contamination of equipment or product by certain substances.

Specifically, osteotomes, gouges, punches, and reamers were being stored uncovered in the stock room, unprotected from humidity and dust.

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OBSERVATION 8

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

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Observation Annotations

Observations intentionally left blank.

* DATES OF INSPECTION:
03/09/2009(Mon), 03/10/2009(Tue), 03/12/2009(Thu)

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