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	09/13/2004 - 09/21/2004 FEI NUMBER 1818910

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Diogo Moreira-Rato, President

FIRM NAME	STREET ADDRESS
Depuy Orthopaedics, Inc.	PO Box 988 700 Orthopaedic Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warsaw, IN 46581-0988	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 I OBSERVED:

OBSERVATION 1

Procedures to control the design process of the device were not complete.

Specifically, risk analysis procedures do not document the mechanism by which unacceptable risks are determined.

Annotation: Reported corrected, not verified.

OBSERVATION 2

Procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements were not complete.

Specifically, procedures used to identify design outputs essential to the proper functioning of devices designed by the firm have not been documented.

Annotation: Reported corrected, not verified.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Robert G. Ruff, Investigator

SEE REVERSE OF THIS PAGE		DATE ISSUED 09/21/2004