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	12/03/2007 - 01/22/2008* FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sara A. Deegan, Sara A. Deegan, Worldwide Vice President

FIRM NAME	STREET ADDRESS
Depuy Orthopaedics, Inc (Ad Hoc Assignment)	700 Orthopaedic Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warsaw, IN 46582-3994	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

Design validation did not ensure that devices conform to defined user/patient needs and intended uses.

Specifically, Depuy's design validation testing (method (b) (4) did not simulate the full range of clinical performance requirement for the Acclaim Total Elbow System. Testing did not simulate device performance while articulating through the (b) (4) which may cause the device to fail.

Annotation: Corrected + Verified CKC 1/22/08

SEE REVERSE OF THIS PAGE

DATE ISSUED CKC 01/22/2008

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*** DATES OF INSPECTION:**
12/03/2007(Mon), 12/04/2007(Tue), 12/05/2007(Wed), 12/06/2007(Thu), 01/22/2008(Tue)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Calvin K. Cook, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
01/22/2008