Orthopaedic
Reconstruction & Trauma
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

T 1-901-396-2121
1-800-821-5700
F 1-901-398-5146
www.smith-nephew.com

We are smith&nephew

June 20, 2012

Ms. Marie Fink
U.S. Food and Drug Administration
New Orleans District Office
2424 Edenborn Ave., Suite 410
Metairie, LA 70001

Dear Ms. Fink:

Smith & Nephew is notifying the U.S. Food and Drug Administration of the company's market withdrawal of the metal liner components of the R3 Acetabular System. The classification of this action as a market withdrawal has been made in cooperation with the New Orleans District Office and CDRH. This report satisfies the report requirements stated in 21.C.F.R. Part 806, *Reports of Corrections and Removals* and 21 CFR 7 subpart C, *Recalls*.

This Market Withdrawal is being initiated based on an internal company decision that these products are not meeting our high standards for performance.

The attachment is provided to satisfy the requirement of 21 C.F.R. Section 806.10 and 21 CFR 7. If you have any questions about the attachment or would like to request additional information, please contact me at 901-399-1970.

Sincerely,

Garry M. Smith
Regulatory Compliance Specialist
Advanced Surgical Devices Division
Smith & Nephew, Inc.
1450 Brooks Rd
Memphis, TN 38116
T 901 399 1970
F 901 566 7975
E-mail: garry.smith@smith-nephew.com

Attachment