November 16, 2015

US Food and Drug Administration
New Orleans District Office
Attn: Marie K. Fink, District Recall Coordinator
2424 Edenborn Ave., Suite 410
Metairie, LA 70001

RE: Advisory Notice – Smith & Nephew Modular Femoral Heads
Removal No. 3005975929-11/16/15-003-R

Dear Ms. Fink:

Smith & Nephew, Inc., as the Authorized US Agent acting on behalf of Smith & Nephew Orthopaedics Ltd., is initiating an advisory notice in accordance with 21 CFR Parts 7 and 806. Additional details related to this notice are provided in the enclosed document.

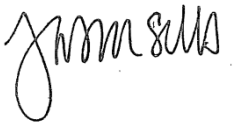
The advisory notice is for the following product:

Product Name:	Smith & Nephew Modular Femoral Heads
Description:	Artificial Hip Replacement Prosthesis
Catalog Numbers:	74121238, 74121242, 74121246, 74121250, 74121254, 74121258, 74121338, 74121342, 74121346, 74121350, 74121354, 74121358, 74121438, 74121442, 74121446, 74121450, 74121454, 74121458, 74121538, 74121542, 74121546, 74121550, 74121554, 74121558
Lot Numbers:	All lots of the affected catalog numbers.
Device Classification:	Class II
Reason for Recall:	Despite the cleared intended use in hemi-arthroplasty patients, Smith & Nephew believes that the MFH can be, and has been, used off-label with a Cobalt Chrome acetabular cup, in a construct that constitutes a MoM bearing. Additionally, as part of the investigation to identify potentially impacted customers, Smith & Nephew discovered that the 16 devices distributed in the United States contained incorrect labeling (Instructions for Use and product label) related to use of this same MFH component with a total hip arthroplasty device that is not available in the United States. While the labeling was not consistent

with that cleared by FDA for the hemiarthroplasty indications noted above, the actual MFH product provided was identical in design and should therefore raise no significant concerns of safety.

If you have any questions regarding this correspondence or need additional information, please contact me at 901-399-5520 or via email at jason.sells@smith-nephew.com.

Kind Regards,



Jason Sells
Director, Regulatory Affairs

Enclosure

Cc: Eric S. Myskowski
Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120