



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Gino J. Rouss
Manager, Regulatory Affairs
Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, Tennessee 38116

Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd
Rockville, MD 20850

Re: P040033/S003
Birmingham Hip Resurfacing (BHR) System
Filed: December 26, 2006
Amended: May 7, September 11, and November 2, 2007, and February 7, and September 18, 2008

Dear Mr. Rouss:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for a manufacturing site located at Smith & Nephew Orthopaedics Ltd., Aurora, Spa Park, Harrison Way, Leamington Spa, Warwickshire, UK, which is to perform final machining, and a manufacturing site located at LPE Medical Ltd, Hannah Way, Gordleton Industrial Estate, Pennington, Lymington SO41 8JD, Hampshire, United Kingdom.

Based upon the information submitted, the PMA supplement is approved subject to the conditions described within the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

If you have questions concerning this approval order, please contact Vertleen Covington at (240) 276-0131.

Sincerely yours,

Gladys Rodriguez
Director
Division of Enforcement B
Office of Compliance
Center for Devices and Radiological Health

Enclosure