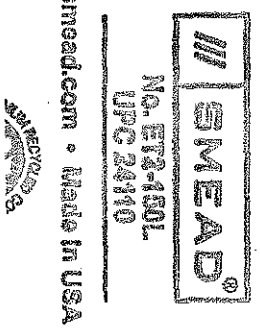

Birmingham Hip Modular Hip
K093095 Withdrawal
21000.68 **US** **2/24/10**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 25, 2010

SMITH & NEPHEW, INC.
ORTHOPAEDICS-RECONSTRUCTION & TRAUMA DIVISION
1450 BROOKS RD.
MEMPHIS, TENNESSEE 38116
UNITED STATES
ATTN: GINO J. ROUSS

510k Number: K093095

Product: BIRMINGHAM HIP (BH) MODULAR HE

Your request for withdrawal and return of the above-referenced Premarket Notification (510(k)) has been received. As a result of your request this file is now considered closed.

Pursuant to 21 CFR 20.29, one copy of the 510(k) will remain in the office of Device Evaluation.

If you decide to resubmit a 510(k) for the above device, a new number will be assigned and your submission will be considered a new submission. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance/approval, you will be in violation of the Federal Food, Drug, and Cosmetic Act. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Orthopaedics
Smith & Nephew, Inc.
1450 Brooks Rd.
Memphis, TN 38116 U.S.A.

901-396-2121
800-821-5700
www.smith-nephew.com

We are smith&nephew

February 24, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: John Goode

RE: K093095 - Birmingham Hip (BH) Modular Head System

Dear Mr. Goode:

The purpose of this letter is to formally request the withdrawal of the Birmingham Hip (BH) Modular Head System Premarket Notification K093095. Should you have any questions related to this request, please do not hesitate to contact me directly at 901-399-6707 or via email at gino.rouss@smith-nephew.com.

Sincerely,

Gino J. Rouss, MS
Manager, Regulatory Affairs
Smith & Nephew Orthopaedics