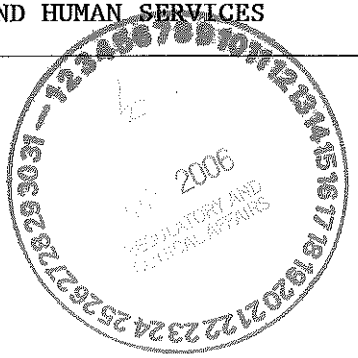
DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 02, 2006

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 BROOKS RD.
MEMPHIS, TN 38116
ATTN: GINO J. ROUSS

510(k) Number: K052808
Product: BIRMINGHAM HIP (BH) MODULAR HIP SYSTEM

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 (HFZ-401) 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 Indust and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. 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 or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

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