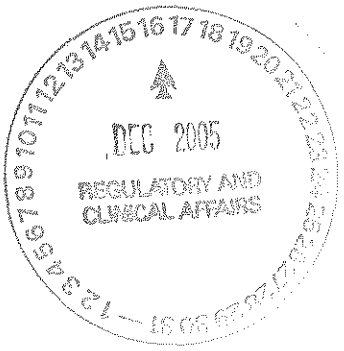
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2005



Mr. Gino Rouss
Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K052808
Trade Name: Birmingham Hip (BH) Modular Hip System
Dated: October 3, 2005
Received: October 5, 2005

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following items:

1. You provided a rationale and justification for including the clinical data for the Birmingham Hip Resurfacing (BHR) System in support of the Birmingham Hip (BH) Modular Hip System in Section 5.6. You stated that from a clinical perspective, the potential failure modes for a metal-on-metal total hip replacement are the same as for a metal-on-metal resurfacing construct except for the potential for femoral neck fractures in the BHR System. However, FDA believes that resurfacing hip systems are used in a different patient population that total hip prostheses. In fact, based on the information you provided in your PMA for the BHR System, which was summarized in FDA's Executive Summary on pp.19-20 of Exhibit 23, you stated that factors such as advanced age, low activity level, and poor bone stock contributed to the physician's decision to perform a total hip replacement in certain patients rather than a hip resurfacing procedure. Therefore, because of differences in the patient populations for resurfacing and total hip systems, there may be differences in adverse events, component fixation, and device performance for the subject device that can not be addressed in the BHR System clinical data. Furthermore, the unique design features of resurfacing hip system compared to total hip prostheses result in different loading environments, which also affect device safety and effectiveness, and which can only be evaluated with clinical data collected on the subject device. Because of the concerns above, we believe the clinical data for a resurfacing hip prosthesis can not be used to predict the safety and effectiveness of a total hip prosthesis. Therefore, please provide clinical data to assess the safety and

effectiveness of your total metal-on-metal device for its intended use in order to support its substantial equivalence to predicate devices.

If collected in the United States, the clinical data would need to be collected as part of an FDA-approved Investigational Device Exemption (IDE) Study. We recommend that you contact us prior to submission of an IDE in order to address any questions related to clinical study design.

Please be advised that in order to pursue clearance of only the hemi-hip components in this 510(k) and not the total hip system discussed above, you may provide a statement that you are removing all of the acetabular cup components from consideration in this 510(k), provide revised indications for use, package insert, 510(k) summary, labeling, and address the additional applicable items outlined below.

In addition to the above major deficiency concerning the need for clinical data, we have noted the following additional issues you should also address in any future correspondence.

2. You stated that the acetabular cups of the subject BH Modular Hip System are the same as the acetabular cups of the Birmingham Hip Resurfacing (BHR) System for hip resurfacing, which is currently under review by the FDA in PMA #P040033. Therefore, you stated that the subject BH Modular Hip System would also allow conversion from a hip resurfacing procedure to a total hip replacement procedure (without disturbing a well-fixed acetabular component) for any BHR resurfacing patient who may eventually need revision of the resurfacing system's femoral component. In order to evaluate whether or not there may be an increase in the generation of metallic wear for such a revision procedure, please provide wear testing of worn acetabular cups (i.e., acetabular cups that have already undergone 5 million cycles of wear testing) and new modular heads for 5 million cycles in a hip simulator. Please compare the results of this wear analysis with the wear testing provided in Exhibits 15 and 17.

3. In Exhibits 13 and 14, you provided an evaluation of the stem and neck strength of the Echelon, Spectron, Emperion, Synergy and Standard Platform Femoral Components using Finite Element (FE) Analysis. On p.15, you stated that all the FE analyses were performed using a validated model based on a size 11 Emperion (Modular) Hip Stem, cleared in K042127. However:

   - Information previously reviewed by the FDA suggests that differences in the selection of material properties, and FE analysis parameters (e.g., model geometry, boundary and loading conditions) may cause FE analysis results to vary significantly (e.g., by as much as 35%);

- In addition, based on your FE analysis results, the worst-case stem strength was 275lb for the Platform size 01 standard offset stem and the worst-case neck strength was 784lbf for the Echelon size 12 high offset stem. These values for stem strength are on the low end of what we have seen for stem strength and we are not aware of devices with neck strengths as low as 784lbf;

- Finally, you did not include a discussion of how the information used to validate the hip stem cleared in K042127 is applicable to the stems for use with the subject device, and you did not discuss where stems were constrained to represent cement potting as it related to their distal design features which include distal flutes, changes in cross-sectional areas, "clothes pin" features, and ribs.

For the reasons outlined above, we believe that the FE analysis should be validated with experimental testing. Therefore, please provide a complete test report containing the results of stem and neck fatigue testing. At least 5 components should be tested to show run-out to 5 million cycles without failure when tested according to ISO 7206-4: 1989 and ISO 7206-6, or similar stem and neck fatigue test methods. To evaluate stem fatigue, stems should be potted 80mm below the center of the femoral head or below design features that may affect the distal stem fatigue strength. The results should be compared to legally marketed predicate devices and a rationale should be provided for the components chosen to represent worst-case constructs.

4. Please provide a table in which you identify each modular femoral head size and the corresponding acetabular cup style (i.e., standard, dysplasia, bridging) and size (i.e., inner diameter and outer diameter) that may be used as a total metal-on-metal hip couple. Please include this information in your revised device package insert.

5. You stated that the HA coating vendor (Plasma Biotal, North Derbyshire, UK) specifies the HA coating thickness to be 75 +/- 20 micrometers. In your PMA, P040033, you included a technical report (TM-05-12) in Attachment 8 of Amendment 12 that clarified that this specification is for flat coupons that are used to set up the plasma spray parameters. You also clarified that the apparent discrepancy between the HA coating thickness used in the specification (75 +/- 20 micrometers) and that measured on the actual component (113 +/-11 micrometers), as reported in Exhibit 37, can be attributed to the component geometry and the measurement technique used. Please include this information in your 510(k).

6. On p.6 you provided a table of femoral stems that are for use with the subject device and identified that the stems in K052426 and K052275 are under review. It appears that these 510(k)s have been cleared for marketing. Therefore, please provide a revised table that clarifies that all of the compatible femoral stems have been cleared.

7. Please include on the indications for use form if the femoral stem components that are for use with the BH System, whether for total or hemi-hip arthroplasty, are for cemented and/or uncemented use. In addition, please include the same indications/intended use on the 510(k) Summary and package insert as on the Indications for Use Form.

8. In your package insert in Exhibit 5, you identify device materials and components including a resurfacing hip system, alumina ceramic acetabular liner, ceramic/ceramic implants, 10Mrad cross-linked polyethylene acetabular liners, etc. It is unclear how these components listed in the current package insert relate to the subject device system. It appears as if you have not provided a package insert which provides adequate instructions for use for the subject device system. Therefore, please provide a revised package insert which provides adequate instructions for use for the Birmingham Hip (BH) Modular Hip System, by:

    a. Removing references to all components and component systems that are not to be used with the subject device; and

    b. Including an adequate device description.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Mr. John S. Goode at (301) 594-2036 ext. 155. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health