DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

March 15, 2006

Sally L. Maher, President
Orthopedic Surgical Manufacturers Association
325 Corporate Drive
Mahwah, New Jersey 07430

Re: Docket No. 2005P-0405

Dear Ms. Maher:

This is an interim response to your petition dated August 3, 2005, which was filed by the Food and Drug Administration (FDA) on September 19, 2005. You submitted additional information on September 19, 2005, which was filed on October 14, 2005. In the petition, you requested reclassification for metal/metal hip prostheses from Class III (premarket approval) to Class II (special controls). You submitted the petition under section 513(e) of the Federal Food, Drug, and Cosmetic Act. FDA is currently undertaking a substantive review of the data submitted and expects to issue a final response to your petition in the next few months.

If you have questions about this interim response, please contact Annette Marthaler of our Regulations Staff at (240) 276-2348.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

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