



Food and Drug Administration
Rockville, MD 20857

September 30, 2005

FILE COPY

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

Dear Ms. Maher:

Your petition requesting the Food and Drug Administration for Reclassification for Metal/Metal Semiconstrained Hip Joint Prostheses with Cemented or Uncemented Acetabular Components was received by this office on 09/19/2005. It was assigned docket number 2005P-0405/CCP 1 and it was filed on 09/19/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0405

ACK 1