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August 3, 2005

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

Subject: Reclassification Petition for Metal/Metal Semiconstrained Hip Joint  
Prostheses With Cemented or Uncemented Acetabular Components 21 CFR  
888.3320 and 888.3330

Dear Sir or Madam:

Enclosed are six copies of an original petition requesting reclassification for metal/metal hip prostheses by FDA from Class III to Class II. This petition is sponsored by the Orthopedic Surgical Manufacturers Association (OSMA) under Section 513 (e) of the Federal Food, Drug and Cosmetic Act as amended.

This is our second effort to gain reclassification and it follows our earlier petition submitted on September 25, 2000 and filed on December 1, 2000. The submission was reviewed by the advisory panel and denied. The denial by the panel and the agency was announced in the Federal Register Vol. 67, No. 173, September 6, 2002. At that time the Deputy Director contended that OSMA had failed to provide any new information to establish that special controls would provide reasonable assurance of the safety and effectiveness of the devices. In addition, the Director determined that clinical and pre-clinical information was insufficient to support downclassification at that time

FDA requested additional clinical data, including longer term follow-up and a higher rate of patient follow-up. The agency also asked for additional pre-clinical data, including validation of hip simulation, non-ideal wear testing and an evaluation of the response to smaller sized metallic wear debris. The evaluation of the response to wear particles may include evaluating retrieved human devices.

*ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION*

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OSMA members have been in contact with members of the Orthopedic Devices Branch and they have been advised of our progress and efforts made to submit a new petition.

If you require additional information or have any questions, please call me at 800-544-2330 x 1492.

Sincerely;



Sally L. Maher  
President, OSMA  
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