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September 13, 2005

Myrna Hanna
Office of Device Evaluation
Document Mail Center (HFZ-215)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
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:

This is to confirm that the information contained in this down classification petition is not considered confidential and may be released to the public.

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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