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September 27, 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

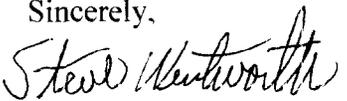
Dear Sir or Madam:

Subject: Amendment to the Reclassification Petition for Metal/Metal Semiconstrained Hip Joint Prostheses With Cemented or Uncemented Acetabular Components 21 CFR 888.3320 and 888.3330 (Petition Submitted August 3, 2005).

The enclosed is an extra copy of an amendment to the subject petition requested by Ms. Marjorie Schulman of the Program Operation Staff within the Office of Device Evaluation at FDA.

If you require additional information or have any questions, please contact Ms. Marjorie Schulman at (301) 594 1190 x. 132 or Ms. Beth Frank at (301) 594-2036 x. 115. You may also contact the undersigned by telephone at 800-544-2330 x 1492.

Sincerely,

for 
Sally L. Maher
President, OSMA
Sally.maher@smith-nephew.com

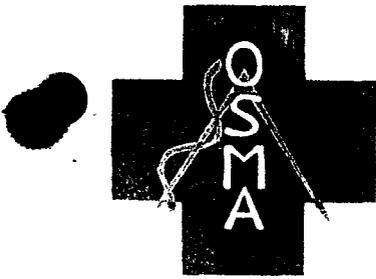
Enclosure

2005P-0405

AMD 1

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION

An Association of Manufacturers Devoted to the Interest of the Surgical Patient
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September 19, 2005

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Dear Sir or Madam:

Subject: Amendment to the Reclassification Petition for Metal/Metal Semiconstrained Hip Joint Prostheses With Cemented or Uncemented Acetabular Components 21 CFR 888.3320 and 888.3330 (Petition Submitted August 3, 2005).

Enclosed are two copies of an amendment to the subject petition requesting reclassification for metal/metal hip prostheses by FDA from Class III to Class II. The reclassification petition, originally submitted to FDA on August 3, 2005, is sponsored by the Orthopedic Surgical Manufacturers Association (OSMA) under Section 513 (e) of the Federal Food, Drug and Cosmetic Act as amended. This amendment contains copies of certain reference articles that were cited in the original petition in support of the reclassification metal-on-metal total hip prostheses. The articles and the bibliography that overlays them are being submitted at the request of the FDA staff member assigned as the lead reviewer of the reclassification petition on September 6, 2005.

If you require additional information or have any questions, please contact the undersigned by telephone at 800-544-2330 x 1492.

for Steve Wentworth
Sally L. Maher
President, OSMA
sally.maher@smith-nephew.com

Enclosure



ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION

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