

**Petition Amendment for
Reclassification for
METAL/METAL SEMI-CONSTRAINED
HIP JOINT PROSTHESES**

VOLUME 1

**PETITION SPONSOR: The Orthopaedic Surgical
Manufacturers Association
(OSMA)**



May 23, 2001

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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

Ladies and Gentlemen:

**Re: Amendment to Reclassification for Metal/Metal Semi-Constrained Hip Joint
Prostheses with Cemented and Uncemented Acetabular Components; 21 CFR
888.320 and 888.330**

Enclosed are 20 copies of an amendment to a petition for the referenced devices requesting reclassification by FDA from Class III to Class II. The petition was submitted to FDA on September 25, 2000 by the Orthopaedic Surgical Manufacturers Association (OSMA) under Section 513 (e)(1) [Title 21 United States Code 360c]. This amendment is in response to additional information for that petition requested by FDA in a letter to OSMA dated December 26, 2000. A copy of that letter is included in this amendment as Exhibit 6.

Please contact the undersigned at (901) 399-6142 if there are any questions or if further information is required.

Sincerely,

Tom Craig

Enclosures

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION

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