



**Reclassification Petition Amendment 1
for
METAL/METAL SEMI-CONSTRAINED
HIP JOINT PROSTHESES**

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



November 28, 2000

Tom Craig, *President*
Bill Christianson, *Vice President*
Mitchell Dhority, *Secretary*
Bob Churinetz, *Treasurer*
Bob Games, *Executive Secretary*

Board of Directors:
Tom Craig
Bill Christianson
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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

**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**

Ladies and Gentlemen:

Enclosed are six 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].

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
An Association of Manufacturers Devoted to the Interest of the Surgical Patient
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