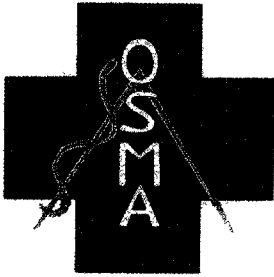


2005P-0405



1338 5 NOV 14 A9:52

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  
sally.maher@smith-nephew.com

2005P-0405

LET 1

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION

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

325 Corporate Drive • Mahwah, NJ 07430

Phone: 201-831-5401 • Fax: 201-831-6411

e-mail: susan.krasny@stryker.com