Petition Sponsors: Orthopaedic Surgical Manufacturers Association (OSMA)

Date: July 21, 2005

Device: Metal-on-Metal Semiconstrained Hip Joint Prostheses with Cemented or Uncemented Acetabular Components

Use Categories: ڤ Diagnostics ڤ Monitoring ڤ Prosthetic

× **Surgical** ڤ Therapeutic ڤ Other

Regulatory Level: II Special Controls

Specific Device Problems: No

Classification System	Yes	No	Not Applicable	Do Not Know
1 Is the device custom made?		X		
2 Although the device is custom made, can standards be applied?			X	
3 Is the device life-sustaining or life supporting?	X			
4 Is the device information derived from use of the device potentially hazardous to life or good health when properly used?			X	
5 Is the device of such a nature that (a) sufficient scientific and med cal data exists from which adequate standards governing the device safety and efficacy could not be established, and (b) development and application of such a standard would be adequate to control the device?	X			
6. Is the device currently in use and marketed in the United States?	X			
7 When the device is used, is it remote from the body?		X		
8 Is the device powered by a non-manual or external or internal source?		X		
9 Will the use of the device or failure of power or device power source present a potential hazard to the patient?			X	
10 Does the device emit and/or inject any form of energy to or into the body?		X		
11 Have the energy levels used been shown to be acceptable?			X	

Classification System	Yes	No	Not Applicable	Do Not Know
12 Will malfunction of the device result in safe energy levels?			X	
13 Does the device use material for contact with the body which is generally acceptable or has known and acceptable properties which can be provided with no additional control requirements?	X			
14 Does the device have any known hazards, limitations, or shortcomings which can be avoided by promulgation of Federal regulations applicable to the device in question?	X			
15 If the device performs some measurement function, should the accuracy, reproducibility, or limitations of the information supplied be clearly indicated to the user by appropriate labeling, instructions or precautions?			X	
16 Does the device have performance characteristics which should be maintained at a satisfactory level, such level having general agreement among user groups?		X		
17 Is the device used with other devices in such a way that the system in which it is used can be hazardous if the system is not assembled, used or maintained in a satisfactory fashion?		X		
18 Is the device potentially hazardous to the fetus or the gonads when properly used?		X		