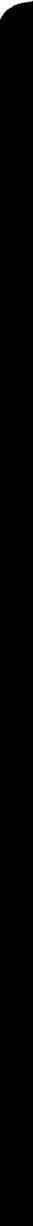




**Classification
Questionnaire**



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: Diagnostics Monitoring Prosthetic
 Surgical Therapeutic 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 medical 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	

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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		