

**COMPLETED CLASSIFICATION  
QUESTIONNAIRE**

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 Medical Device Classification System

Petition Sponsors: Orthopedic Surgical Manufacturers Association

Date:

Device: Hip Prosthesis, Metal/Metal Semi-Constrained Cemented or Uncemented

Use Categories:    \_\_\_ Diagnostics            \_\_\_ Monitoring    \_\_\_ Prosthetic  
                            X  Surgical                    \_\_\_ Therapeutic    \_\_\_ Other

Regulatory Level: I. General Controls  
                           II. Special Controls  X   
                           III. Pre-Market Approval

Specific Device Problems \_\_\_ Yes  X  No

Classification System	Yes	No	Do Not Know	Regulatory Level	Question Scheme
1. Custom Made		X			
2. Custom Made Standard?	N/A	N/A			
3. Life Sustaining		X			
4. Potentially Hazardous to Life, Good Health?		X			
5. (a) Can Standards be Developed Now; and (b) Would Standard be Adequate?	X				
6. Marketed in the United States	X				
7. Remote from Body?		X			
8. Powered?		X			
9. Failure of Power: Hazardous to Patient?	N/A	N/A			
10. Introduce Energy into body?	N/A	N/A			
11. Acceptable Energy Levels?	N/A	N/A			
12. Safe Energy Levels if Malfunction?	N/A	N/A			
13. Material Regarded as Safe without Standard?	X				
14. Prescriptions Needed? Limitation, Hazards, Difficulties, Problems	X				
15. Labeling Instructions Or Precautions of Measurement Function	N/A	N/A			
16. Performance Standards?		X			
17. Special Safety Systems Considerations?		X			
18. Potentially Hazardous to Fetus and/or Gonads?		X			