SECTION III

CFR CLASSIFICATION OF METAL/METAL SEMI-CONSTRAINED HIPS

A. Current CFR Classifications of Metal/Metal Semi-Constrained Hip Prostheses

888.3320 Hip joint, metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement. (888.3027).

(b) *Classification.* Class III.

888.3330 Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended for use without bone cement (888.3027).

(b) *Classification.* Class III.

B. Requested Classification

Based upon the information contained in this petition, the sponsor proposes the following changes to the descriptions and identifications under the device classification codes listed in 21 CFR 888.3320 and 888.3330 for total hip prostheses. Please note that all proposed changes appear in bold face type. The description used for porous coated prostheses is identical to that used in 888.3358.

888.3320 Hip joint, metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement. (888.3027).

(b) Classification. **Class II.**

888.3330 Hip joint, metal/metal semi-constrained, **with a porous- coated, uncemented acetabular** prosthesis.

Identification. A hip joint metal/metal semi-constrained, **porous-coated uncemented acetabular** prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device is designed for use with bone cement and/or to achieve biological fixation to bone without the use of bone cement.
Classification. **Class II.**