

**EXHIBIT 1**

## 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.

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 an uncemented acetabular component, prosthesis.

(a) *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 **has a femoral component made of a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of a metal articulating bearing surface in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The acetabular shell has a porous coating made of, in the case of Co-Cr-Mo substrates, beads of the same alloy, and in the case of Ti-6Al-4V substrates, fibers of commercially pure titanium or Ti-6Al-4V alloy. The porous coating has a volume porosity between 30 and 70 percent, and average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. The generic type of device has a design to achieve biological fixation to bone without the use of bone cement. The femoral component is intended to be fixed with or without bone cement.**

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

(c) *Identification.* A hip joint metal/metal semi-constrained, **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 **has a femoral component made of cobalt-chromium-molybdenum (Co-Cro-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of a metal articulating bearing surface in a metal shell made of Co-Cro-Mo or Ti-6Al-4V. The acetabular shell has no porous coating and fixation is achieved by means of threads on the metal**

shell, or by other uncemented means. The femoral component is intended to be fixed with or without bone cement.

*(d) Classification. Class II – This device as described in “(c) Identification” will be subject to the availability of clinical data in support of substantial equivalence in addition to the other special controls listed in this regulation.*

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(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.

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#### B. Requested Classification

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(c) *Identification.* A hip joint metal/metal semi-constrained, **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 has a femoral component made of cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of a metal articulating-bearing surface in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The acetabular shell has no porous coating and fixation is achieved by means of threads on the metal

shell, or by other uncemented means. The femoral component is intended to be fixed with or without bone cement.

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