interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination of polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve.

(b) Classification. Class II.

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

(a) Identification. A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.”

[67 FR 21173, Apr. 30, 2002]

§ 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.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 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 prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).
§ 888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.

(a) Identification. A hip joint metal/composite semi-constrained cemented 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 component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene reinforced with carbon fibers composite. Both components are intended for use with bone cement (§888.3027).

(b) Classification. Class II.

§ 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.

(a) Identification. A hip joint metal/polymer semi-constrained cemented 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 includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§888.3027).

(b) Classification. Class II.

§ 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

(a) Identification. A hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a device intended to be implanted to replace a hip joint. This device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. The two-part femoral component consists of a femoral stem made of alloys to be fixed in the intramedullary canal of the femur by impaction with or without use of bone cement. The proximal end of the femoral stem is tapered with a surface that ensures positive locking with the spherical ceramic (aluminium oxide, $\text{Al}_2\text{O}_3$) head of the femoral component. The acetabular component is made of ultra-high molecular weight polyethylene or ultra-high molecular weight polyethylene reinforced with nonporous metal alloys, and used with or without bone cement.

(b) Classification. Class II.

§ 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

(a) Identification. A hip joint metal/polymer/metal semi-constrained porous-coated uncemented 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 an ultra-high molecular weight polyethylene articulating bearing surface fixed in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The femoral stem and acetabular shell have 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