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, 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).

(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.”


### § 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 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.