

§ 888.3390

polyacetal cemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis is intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type

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of device may be fixed to the bone with bone cement (§ 888.3027) or implanted by impaction.

(b) *Classification.* Class II.

§ 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic resurfacing prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

(b) *Classification.* Class II.

§ 888.3410 Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer or ceramic/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. 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 cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 3, 2005, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before January 3, 2005, been found to be substantially equivalent to a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented