§ 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

(a) Identification. A hip joint femoral (hemi-hip) metallic cemented or uncemented 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 component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with bone cement (§ 888.3027) as well as designs which have large window-like holes in the stem of the device and which are intended for use without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) Classification. Class II.

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

(a) Identification. A hip joint (hemi-hip) acetabular metal cemented prosthesis is a 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 (hemi-hip) acetabular metal 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 (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal (hemi-hip) acetabular metal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

(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 (hemi-hip) acetabular metal 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 (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal (hemi-hip) acetabular metal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.