§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) Identification. A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device intended to be implanted to replace part of a knee 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 a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.
§ 888.3580 Knee joint femoral (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) Identification. A knee joint femoral (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to replace a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those prostheses intended for use without 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 knee joint femoral (hemi-knee) metallic resurfacing uncemented prosthesis described in paragraph (b)(2) of this section 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 knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femoral (hemi-knee) metallic resurfacing uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) Identification. A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint. The device limits translation in one or more planes. It has no linkage across-the-joint. This prosthesis is intended to be used without bone cement (§ 888.3027).

(b) Classification. Class II.

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) Identification. A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is a device intended to be placed in commercial distribution before May 28, 1976. Any other knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is intended for use without bone cement (§ 888.3027).

(b) Classification. Class II.

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) Identification. A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. This prosthesis is intended to replace one humeral condyle or one humeral head and one glenoid component. This prosthesis is intended for use without bone cement (§ 888.3027).