§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

(a) Identification. A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. 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 a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for use with bone cement (§ 888.3027). The patellar component is designed to be implanted only with its femoral component.

(b) Classification. Class II. The special controls for this device are:

(1) FDA's:

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90–1)."
(iii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement."
(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices."

(2) International Organization for Standardization's (ISO):

(3) American Society for Testing and Materials:

(i) F 75–92 "Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material."
(iv) F 1044–95 "Test Method for Shear Testing of Porous Metal Coatings."
(v) F 1108–97 "Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants."
(vi) F 1147–95 "Test Method for Tension Testing of Porous Metal Coatings."
(viii) F 1672–95 "Specification for Resurfacing Patellar Prosthesis."

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

(a) Identification. A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis
§ 888.3560 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) Identification. A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, 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 consist

§ 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

(a) Identification. A knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace 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 I (special controls). The special control is FDA’s guidance: “Class I Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.” See §888.1 for the availability of this guidance.

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

(a) Identification. A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace a knee 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, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, 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.