§ 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:

(i) ‘‘Use of International Standard ISO 10993 ‘‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing.’’’

(ii) ‘‘510(k) Sterility Review Guidance of 2/12/90 (K90–1).’’

(iii) ‘‘Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Approaching Bone or Bone Cement.’’

(iv) ‘‘Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices.’’ and

(v) ‘‘Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components.’’ and

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


(iv) ISO 5833:1992 ‘‘Implants for Surgery—Acrylic Resin Cements.’’


(vi) ISO 6018:1987 ‘‘Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling.’’


(3) American Society for Testing and Materials:

(i) F 75–92 ‘‘Specification for Cast Cobalt–28 Chromium–6 Molybdenum Alloy for Surgical Implant Material.’’


(iii) F 799–96 ‘‘Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants.’’

(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.’’

(vii) F 1328–95 ‘‘Specification for Wrought Cobalt–28 Chromium–6 Molybdenum Alloy for Surgical Implants.’’

(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.
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§ 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 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.

§ 888.3565 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 is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial base plate.

(b) Classification. Class II (special controls). The special control is FDA’s guidance: “Class II 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.

[68 FR 14137, Mar. 24, 2003]

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

(a) Identification. A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented 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 III.

§ 888.3570 Knee joint patellofemorotibial metal/polymer semi-constrained cemented prosthesis.

(a) Identification. A knee joint patellofemorotibial polymer/metal/polymer semi-constrained 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 knee joint patellofemorotibial polymer/metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.