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across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained cemented 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 consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.

(a) *Identification.* A knee joint femorotibial (uni-compartmental) metal/polymer porous-coated 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 surface. 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 baseplate.

(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]

§ 888.3540 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 Apposing 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):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: