§ 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 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:


(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


(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,”


(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 1357-94 “Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants,” and

(viii) F 1672-95 “Specification for Resurfacing Patellar Prosthesis.”