§ 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.

(a) Identification. A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component, 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 or components 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 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 VerDate Mar<15>2010 18:43 May 19, 2014 Jkt 232077 PO 00000 Frm 00560 Fmt 8010 Sfmt 8010 Q:\21\21V8.TXT ofr150 PsN: PC150