Food and Drug Administration, HHS

§ 888.3100  Ankle joint metal/composite semi-constrained cemented prosthesis.

(a) Identification. An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle 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 talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (§888.3027).

(b) Classification. Class II.

§ 888.3110  Ankle joint metal/polymer semi-constrained cemented prosthesis.

(a) Identification. An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces.