§ 888.3790 Wrist joint metal constrained cemented prosthesis.

(a) Identification. A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.

§ 888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) Identification. A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) Classification. Class II.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) Identification. A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.


§ 888.4200 Cement dispenser.

(a) Identification. A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in